CLINICAL INVESTIGATION PROGRAM REPORT

DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FT GORDON, GA 30905

FY 94

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CLINICAL INVESTIGATION

PROGRAM REPORT

01 October 1994

CONTROL SYMBOL: RCS MED-300 (R)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

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The illustration used on the cover this year is taken from Robert Burton's classic, *Anatomy of Melancholy*, first published in 1621. This highly popular text by a non-physician Anglican cleric represented the height of classical psychiatry. It basically is the update of Galen's *Melancholia* to cover a millennium and a half of progress. Both works assume the validity of the Pythagorean-Empedoclean theory of four elements (air, water, fire and earth) , four humors (blood, phlegm, yellow bile and black bile), and four qualities (hot, cold, moist and dry). These factors thought to affect different organs at different times. Assorted empirical elements were applied to all of medicine of which psychiatry was a part. This system presupposed the Aristotelian system of three "souls" affecting the mind *(psyche)*: the vegetative soul common to all living things, the animal soul common to animals and man, and the rational soul unique to man.

With this theoretical framework, good physicians in common with most scholars accepted numerous etiologies for delusions, irrationality, and madness. Imbalances in the diet, environment, or the humors were routinely blamed for temporary or acquired aberrations. Changes were usually recommended based on a given physician's interpretation of his patient's condition. Galen, always the eclectic in medicine, favored the ongoing control of one's passions (those influences of the animal soul disturbing the rational soul). He suggested various ascetic practices under the guidance of a wise mentor. This accords with the basic practice of monasticism of the early and medieval church, both east and west. The monasteries had assumed the duties of most scholarly endeavor following the collapse of the secular government in the western Roman Empire. The growth of medicine came to be influenced by the Catholic Church which was concerned for the weak and the poor. Hospitals came to be associated with monasteries and their herbal gardens as the last bastion of compassionate learning and medicine. Previously medicine was primarily for those who could afford it and for the military who needed good health to protect the empire. In the Byzantine part of the Roman Empire, no collapse of government occurred until the 15th century with the triumph of the Turks over Byzantium. Charitable institutions for orphans, the aged, and for the mentally sick were established by the Emperor Justinian in the sixth century. Humane medicine flourished under Islam, largely through Christian and Jewish physicians. The Prophet Mohammed had a Christian physician which established a tradition of tolerance for their services. Mental hospitals similar to those inherited from Byzantium were established in the thirteenth century.

Much of modern popular culture, and even some academic instruction, has attempted to portray the Middle Ages (often called the Dark Ages by anti-cleric Eurocentrics) as being totally obsessed with the demonic as the etiology of all mental illness until the modern "enlightenment." This approach fails to distinguish between lay, popular notions and professional approaches of the times. Although both Christian and pagan scholars from antiquity have recognized influences on the mind by spiritual forces, this was never regarded by the educated as the first place to look. The Greek philosophers, including Plato, recognized a "divine madness" distinct from natural madness. The former included prophetic madness (from Apollo), religious madness (from Dionysus), poetic madness (from the Muses), and erotic madness (from Aphrodite and Eros). Christian thinkers also accepted this structure except that the spiritual influences were narrowed to the angelic and demonic. This influence was regarded as limited to the realm of moral and rational thought and did not exclude natural or material causes. The Christians, unlike the pagans, had a commitment to the weak and vulnerable and did not resort to exposure (infanticide) or abortion for defective offspring. Both of these practices were explicitly prohibited in the *Didache*, a first or second century book of instruction for Christians. This concern included the mentally ill as objects of their charity.

A variety of sources indicate that persons with psychiatric disorders (in modern diagnostic terminology) were generally regarded as physically ill and treated with the kindness and thoughtfulness it entailed. The English Crown had jurisdiction over the mentally ill from at least the thirteenth century with specific duties to care for that person's estate while incapacitated. The crown was restricted by *Prerogativa Regis* from taking anything for itself from that person's estate. Distinctions were made between natural fools (congenital intellectual impairment) and *non compos mentis* (acquired impairment). The latter category was a broader psychiatric diagnosis but a potentially reversible one. A jury of twelve persons was required to establish the status and the handling of the persons affairs. This secular jury was often call an inquisition. Part of their charge in the idiocy writ was to determine whether there were intervals of lucidity. The term for acquired problems later came to be called lunacy. The ability to handle simple coinage questions and knowing one's present location and some memory tests. Reasons for the onset of current lunacy were usually ascribed to specific times and events (e.g. the time of a fever, a blow to the head, or a great fright).

Critics of the handling of mental illness during Medieval times point to the publication of *Malleus Maleficarum* (1484) and the Inquisition. The emphasis on witchcraft and sorcery tended to be a very late phenomenon which interestingly coincided with the Enlightenment and Renaissance. The *Encyclopedia of Bartholomaeus* dates to about 1230 by a Franciscan monk and theologian. It deals with mental illness in terms of natural causes rather than demonic or supernatural. He tries to localize the proximate cause of madness to the brain area surrounding the lateral ventricles. This was a widely used book in universities and was one of the early books to be published on the printing presses in 1470, only fourteen years after the Gutenberg Bible. It recommended as follows:

> The medicines of the (suffering person) is, that they be bounde--that they hurt not them selfe and other men. And namely suche shall be refreshed and comfortid--and withdrawen from cause and mater of drede and besy thoughtes. And they muste be gladded with instrumentes of Musike--and some deale be occupied. And at the last if purgations and electuaries suffisen not, they shall be holpe and crafte of surgery.

Unfortunately much of the superstition that reappeared in medicine following the Crusades came from the reappearance through the most "scientific" of the medical practitioners of astrology. This seemingly accompanied the Arabic medicine introduced during that time. Astrology had been debunked thoroughly by St. Augustine, the towering fourth century theologian from North Africa (e.g. *The City of God*). Nonetheless astrology re-emerged during the late Middle Ages as part of scientific medicine. (Kepler attempted to reform astrology as part of his Copernican reform of astronomy and Isaac Newton left huge manuscripts on his private study of alchemy.)

The Inquisition was instituted in 1233 by Pope Gregory IX to combat the Catharist heresy (a gnostic variant) in southern France. It was originally aimed at heretics, not witches. Witchcraft was considered to be a secular offense since it was intended to harm others or their property. In 1080 and earlier Pope Gregory had written Harold the Simple of Denmark disapproving "the custom of attributing to priests and women all tempests, sickness, and other bodily misfortunes." By the late fifteenth century and into the sixteenth century the Catholic Church tried to resist the free thinking movement and the reformists by dealing with dissent as witchcraft. Leading protestants also accepted this faulty analysis and became witch hunters in many places--the one American example being prominent.

The radical changes being faced by society through the seventeenth century were widespread, especially as it affected the underlying theoretical assumptions. Medieval scholars clung to the classical authorities--Galen in medicine. Experimental science was considered to be part of empiricism, a

lower level of philosophy in their minds. Folk medicine of this time was of a definitely lower order and included much superstition. All of medicine and science was believed to rest on certain organizing principles which were assumed in a largely unquestioned manner. This is still true but the organizing principles are different.

Modern biological psychiatry is probably not too far from Galen with changed names for some of the vapors and humors and which extracts modified by which chemicals is efficacious in treating various aspects of melancholia. It is the psychological structure, based as it is on widely different assumptions about the nature of man and his being, which would be dismaying to an ancient physician alive today. Galen was an eclectic with a keen eye for accurate information. His image was tarnished by those who clung to him slavishly without looking to his methods for gaining new knowledge. In an analogous way many lay superstitions and folk beliefs still play a prominent role in folk medicine. Our age has its share of "New Age" beliefs that blend the old with distortions from genuine research. Who has not seen patients who cling to the value of "natural" or "organic" foods or treatments as a talisman against disintegrating forces.

The tensions inherent in studying psychiatry in a rational manner raises not only the issues affecting the scientific ones surrounding the brain as an organ which supports thought and which can malfunction just as any organ can but also the recognition that something regarding our nature as a rational being resides within this apparatus. This being can make choices within various contexts and limitations to include the consequences of earlier choices. One's understanding of the nature of man is still a primary determinant in the type of science one attempts to follow. It makes studying the mind more complex than studying the brain much as studying a functioning computer is more complex than simply analyzing its hardware. We have "medicalized," or attempted to do so, many problems ranging from chemical dependence problems to urban violence with limited success since only part of the pathology resides in the brain and some is in the mind. We have great success with new psychotropic drugs which provide immense relief to various forms of melancholia tied to receptor imbalances. We have a blight of self medication of psychotropic drugs by a lay population trying to treat the torments of their minds arising from poor choices made in the past. The lines are never clear here as we attempt to design research which can sort the one from the other. As caring, humanistic physicians we may attempt to ease feelings of guilt and forget that if we blur excessively the responsibility for bad choices we equally blur the credit for good choices and destroy the moral rational personhood in favor of an automaton in need of reprogramming. Research in this area will never be easy. It can be made more difficult by misguided notions of the nature of man and his relationship to the universe.

The psychiatric research at EAMC reflects this diversity and conflicts. Especially exciting has been a long term project looking at first break psychotics who experience this first break under the stresses of entering the military. These soldiers have not been medicated or institutionalized and reflect more clearly the biological aspects of possible schizophrenia. Many eventually develop some form of chronic or episodic schizophrenia. Brain imaging and skin biopsies have been quite exciting in this regard. Caution is still in order since so many previous biological differences have come to naught.

Kent M. Plowman

Kent M. Plowman, PhD, MD
Colonel, Medical Corps
Chief, Dept. Clin. Invest.

References:

Kroll J: A reappraisal of Psychiatry in the Middle Ages. *Arch. Gen. Psychiatry* 29:276-283, 1973.
Tourney G: The Physician and Witchcraft in Restoration England. *Med. History* 16:143-155, 1972.
Neugebauer R: Treatment of the Mentally Ill in Medieval and Early Modern England: A Reappraisal. *J. History Behav. Sc.* 14:158-169, 1978.
Schoeneman TJ: The Role of Mental Illness in the European Witch Hunts of the Sixteenth and Seventeenth Centuries: An Assessment. *J. History Behav. Sc.* 13:337-351.

UNIT SUMMARY - FISCAL YEAR 1994

A. Objective:

The objective of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach:

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing:

Name	Rank	MOS	Title
Plowman, Kent M.	COL	61F00	Chief
Runyan, Dennis	COL	63F	Chief, Biometrics and Statistical Design
Craft, David	MAJ	71A67	Immunologist/Microbiologist
Tobias, Stephen	MAJ	64A00	Veterinarian
Vlach, Kim	CPT	64A00	Veterinarian
Czerwinski, Steven	CPT	71B67	Biochemist
Williams, Linda E.	SSG	92B30	NCOIC
Figueroa, Ronald J.	SSG	91K30	NCOIC
Mason, Chana L.	SGT	91K20	Med Lab NCO
Collins, Demetrius D.	SPC	91T10	Veterinary Technician
Naylor, Timothy L.	SPC	91K10	Med Lab Specialist
Horner, Jack A.	GM13	01301	Asst C, Res Histologist
McPherson, James C. III	GS13	01320	Biochemist, PhD
Runner, Royce	GS11	00644	Medical Technologist
Best, Norma	GS9	00644	Medical Technologist
Chaung, Augustine, H. PhD	GS9	00644	Medical Technologist (MRDC Grant)
Ferguson, Phyllis	GS5	00303	Protocol Coordinator
Nelson, Manuela	GS5	00404	Biological Lab Tech
Reisenger, Rebecca	GS4	00312	Clerk-Steno
Silas, Mary Ann	GS4	00303	Clinical Protocol Assistant
Reid, Tilda	WG2	00404	Biological Lab Tech

Officer: 4 authorized; 5 required; 5 assigned
Enlisted: 5 authorized; 9 required; 4 assigned
Civilian: 7 authorized; 13 required; 10 assigned

One third-party FACT physician assistant employee in Pulmonary Service.
One third-party FACT research assistant employee in Pulmonary Service.
One third-party FACT clerk employee in Pharmacy.
One third-party FACT study site facilitator/clinical research nurse employee in Clinical Investigation.

d. Funding:

TYPE	Fiscal Year 93	Fiscal Year 94
Civilian personnel to include benefits	305,873.97	358,100.00
Consumable supplies	197,964.03	145,200.00
Civilian contracts to include consultants	6,829.00	11,600.00
TDY	4,856.40	3,400.00
Publications	619.40	899.25
CEEP	86,590.31	378,425.00
MEDCASE	218,820.71	413,149.14
Total	1,318,424.82	1,310,773.39

GRANT FUNDING:

Defense Women's Health Research Program:

1) "The Effects of Estrogen and Progesterone Levels on Osseointegration of Dental Implants". FY94: $68,880.00
2) "The Incidence of Localized Osteitis in Female Soldiers Using Norplant Contraceptive". FY94: $41,421.00
3) "The Effect of Levonorgestrel (Norplant) on the Immune Regulation of Bone Morphogenesis". FY94: $12,500.00
4) "Efficacy of Case Management in a Military Medical Center". FY94: $89,223.00

E. Progress:

Protocol Disposition FY 94

	Completed	Terminated	Ongoing to FY 94
FY 78	1		
FY 85			1
FY 87		1	1
FY 89			1
FY 90	5	2	9
FY 91	5	1	9
FY 92	7	3	22
FY 93	15	13	26
FY 94	2	13	62
TOTAL	35	32	131

Number of resident and fellowship programs: 1 Fellowship & 13 Resident
Number of programs using Clinical Investigation: 15
Number of residents and fellows on approved protocols: 41
Number of approved protocols held by this group: 41

Other training programs that use Clinical Investigation: Graduate students, transitional interns, psychology interns, nurse anesthetist, radiology, pathology, health care administrators, and oral maxillofacial surgery:
1 Transitional intern program (6 interns)
1 Psychology intern program (6 interns)
1 Radiology intern program (4 interns)
1 Emergency Medicine intern program (4 interns)
1 Oral Maxillofacial Surgery intern program (4 interns)
1 Pathology intern program (2 interns)
1 Health Care Administrator intern program (2 interns)
1 Nurse Anesthetist intern program (4 interns)

Number of approved protocols held by this group: 32

Number of hospital staff members on approved protocols: 55
Number of approved protocols held by this group: 87

Drug evaluation/comparison studies: 33
Treatment evaluation/comparison studies: 54

RESEARCH AWARDS

Recipient of

The Twelve Annual DDEAMC Resident Research Award

was

Captain Samuel K. Miller, MC

for his paper

"The Use of Passive Drainage in Breast Biopsy Procedures"

The paper was based on Protocol 93-65 and was presented at the Eisenhower Army Medical Center Annual Resident Research Presentation Day, May 1994.

Recipient of

The Eighth Annual Dental Resident Research Award

was

Major R. Terry Ellis, DE

for his paper

"Parotid Gland Biopsy and Transbronchial Lung Biopsy in the Diagnsosi of Sarcoidosis: A Comparison Study"

The paper was based on Protocol 91-62.

INSTITUTIONAL REVIEW COMMITTEE

Clinical Investigation and Human Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
Chief, Department of Ministry and Pastoral Care
Chief, Nursing Education and Staff Development
Chief, Department of Pathology
Signal Center Representative, Fort Gordon, Georgia
Research Director, Department of Family Practice
Research Director, Department of Psychiatry and Neurology
Veterinarian, Department of Clinical Investigation
Medical Center Judge Advocate
Chief, Nucleur Medicine Service
Radiation Safety Officer
Chief, Medical Records Administration Section

Animal Care and Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Veterinarian, Department of Clinical Investigation
Signal Center Representative, Fort Gordon, Georgia

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Code:

O - Ongoing
C - Completed
T - Terminated
W - Withdrawn
P - Published
PR - Presented

PUBLICATIONS FY 94

DEPARTMENT OF CLINICAL INVESTIGATION

Pashley DH, Ciucchi B, Hidehiko S, and Horner, JA: Permeability of Dentin to Adhesive Agents. Quintessence International 1993; 24:618.631.

Shono T, Sano H, Takatsu T, Hosoda H, Ciucchi B, Horner, JA, and Pashley DH: Study of Marginal Leakage of the Adhesive Composite Restoration. Adaptation versus Leakage. Jap. J. Conserv. Dent.; 36(6): 1582-1589, 1993.

Sano H, Shono T, Sonoda H, Takatsu T, Ciucchi B, Horner JA, Carvalho RM, and Pashley DH: Tensile Bond Strength versus Surface Area for Dentin Bonding. Jap. J. Conserv. Dent.; 37(3):882-887, 1994.

Sano H, Shimada Y, Shono T, Takatsu T, Ciucchi B, Horner JA, and Pashley DH: Preliminary Study on Tensile Strength of Mineralized and Demineralized Dentin. Jap. J. Conserv. Dent.; 37(2):379-383, 1994.

Steflik DE, Sisk AL, Parr GR, Gardner LK, Hanes PJ, Lake FT, Berkery DJ and Brewer P: Osteogenesis at the Dental Implant Interface: High Voltage Electron Microscopic and Conventional Transmission Electron Microscopic Observations. J. Biomed. Mat. Res.; 27(6):791-800, 1993.

Steflik DE, Sisk AL, Parr GR, Lake FT, Hanes PJ, and Brewer P: TEM and HVEM of Osteogenesis at the Implant Interface. J. Dent. Res.; 72:355, 1993.

Gardner LK, Steflik DE, Parr GR, Sisk AL, Hanes PJ, Brewer P, and Horner J: SEM Morphometry of the Bone Interface to Prosthodontically Loaded Implants. J. Dent. Res.; 72:273, 1993.

Steflik DE, Lake FT, Sisk AL, Parr GR, Hanes PJ, Brewer P, and Berkery DJ: TEM Evaluation of Bone Remodeling at the Implant Interface. J. Dent. Res.; 73, 1994.

Steflik DE, Parr GR, Sisk AL, Hanes PJ, Lake FT, Berkery DJ, Brewer P, Patterson JW, Adams B, and Yavari J: Ultrastructure of Bone Remodeling and Histomorphometry of the Bone-Implant Interface: A Comparative Dental Implant Study. Trans. Soc. Biomat.; 1994.

Craft DW, Williams LE, Kozar MP, Thomas EE, and Forney JR: Out of the Ivory Tower: Evaluation of Rapid Diagnostic Human Immunodeficiency Virus (HIV) Test Kits in a Field Environment. J. of Military Med. Lab. Sc.; Vol. 23, 0-5, 1994.

Nang RN, Sutherland DE, Miller P, and Haburchak DR: Reported Reduction in Sexual Activity after Discovery of HIV Seropositivity in US Soldiers, The Journal of the US Army Medical Department; Sep/Oct 1993.

Kriegel DL, Jones CD, Runner RR, Black JB, Chuang AH, McPherson JC III, and McPherson JC Jr: "Glass Effect" on Red Blood Cells (RBCs) May Be Affected by Charge As Well As pH. Ga J. Sci.; Vol. 52, Page 64-65, 1994.

Ballard JB, Stringer MD, Runner RR, Black JB, Chuang AH, McPherson JC III, and McPherson JC Jr: Anti-Freeze Protein and Rouleau Formation. Ga J. Sci.; Vol. 52, Page 59, 1994.

Stringer MD, Ballard JB, Chuang AH, Black JB, Runner JC, McPherson JC III, and McPherson JC Jr: Anti-Freeze Protein and the Mechanical Fragility of Rat Red Blood Cells. Ga J. Sci.; Vol. 52, Page 58-59, 1994.

Jones CD, Kriegel DL, Chuang AH, Black JB, McPherson JC III, and McPherson JC Jr: Comparison of Red Cell Deformability in Polyvinyl Pyrrolidone and Dextran. Ga J. Sci.; Vol. 52, Page 58, 1994.

DENTAL ACTIVITY

Pashley DH, Ciucchi B, Hidehiko S, and Horner, JA: Permeability of Dentin to Adhesive Agents. Quintessence International 1993; 24:618.631.

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Steflik DE, Parr GR, Sisk AL, Hanes PJ, Lake FT, Berkery DJ, Brewer P, Patterson JW, Adams B, and Yavari J: Ultrastructure of Bone Remodeling and Histomorphometry of the Bone-Implant Interface: A Comparative Dental Implant Study. Trans. Soc. Biomat.; 1994.

Galvan DA, Ciarlone AE, Pashley DH, Kulild JC, Primack PD, and Simpson MD: Effect of Smear Layer Removal on the Diffusion Permeability of Human Roots. Journal of Endodontics; Vol. 20, No. 2, February 1994.

Singh G, O'Neal RB, Brennan WA, Strong SL, Horner JA, and VanDyke TE: Surgical Treatment of Induced Peri-Implantitis in the Micro Pig - Clinical and Histological Analysis. Journal of Periodontology 64; 10:984-989, Oct 1993.

Dragolich WE, Pashley DH, Brennan WA, O'Neal RB, Horner JA, and VanDyke TE: An in vitro Study of Dentinal Tubule Occlusion by Ferric Oxalate. Journal of Periodontology 64:11; Nov 1993.

Guy SC, McQuade MJ, Scheidt MJ, McPherson JC, Rossmann JA, Vandyke TE: Invitro Attachment of Human Gingival Fibroblasts to Endosseous Implant Materials. Journal of Periodontology; 64(6):542-546, 1993.

Liewehr FR, Kulid JC, and Primack PD: Obturation of a C-Shaped Canal Using an Improved Method of Warm Lateral Condensation. Journal of Endodontics 1993; 19:474-477.

Shahan MH, Chuang AJ, Brennan WA, Dirksen TR, VanDyke TE, and McPherson JC: The Effect of Chlorhexidine Irrigation on Tensile Wound Strength. J. Periodontal 1993; 64:719-722.

Longfield JN, Brundage J, Badger G, Vire D, Milazzo M. Ray K, Gemmill R, Magruder C, Oster CN, and Roberts: Look-Back Investigation after Human Immunodeficiency Virus Seroconversion in a Pediatric Dentist, The Journal of Infectious Disease 1994; 169:1-8.

Tewfik HM, Pashley DH, Horner JA, and Sharaway MM: Structural and Functional Changes in Root Dentin Following Exposure to KTP/532 Laser. Journal of Endodontics; 19(10):492-7, Oct 1993.

Koutsi V, Noonan RG, Horner JA, Simpson MD, Matthews WG, and Pashley DH: The Effect of Dentin Depth on the permeability and Ultrastructure of Primary Molars. Pediatric Dentistry; 16(1):29-35, Jan 1994.

DEPARTMENT OF FAMILY PRACTICE

Epperly TD: The Older Athlete. Sportsmedicine for the Primary Care Physician; 2nd Edition, CRC Press, Boca Raton, Florida, 187-194, May 1994.

Epperly TD and South-Paul J: Fetal Surveillance. Consultations in Obstetrics and Gynecology; 5(4):276-285, Dec 1993.

Blount BW, Hart G, and Ehreth JL: A Description of the Content of Army Family Practice. Journal of the American Board of Family Practice; 6(2):143-52, Mar 1993.

Blount BW, and Curry A: Caring for the Bicultural Family: The Korean-American Example. Journal of the American Board of Family Practice; 6(3):261-8, May 1993.

Blount BW, Krober MS, Gloyd SS, Kozakowski M, and Casey L: Nutritional Status of Rural Bolivian Children. Military Medicine; 158(6):367-70, Jun 1993.

Thompson BA, Blount BW, and Krumholz TS: Treatment Approaches to Bruxism. American Family Physician; 49(7):1617-22, May 1994.

DEPARTMENT OF MEDICINE

Faircloth DN, Tenholder MF, Whitlock WL, and Downs RH: Pulmonary Dysfunction Secondary to Mandibular Retrognathia in Marfan's Syndrome. Chest 1994; 105:1610-13.

Hilburn RB, Bookstaver D, and Whitlock WL: Angiotension-Converting Inhibitor Hepatotoxicity: Further Insights. The Annals of Pharmacology; 27:1142, September 1993.

Tenholder MF and Whitlock WL: Can the Nebulizer Survive? Arch Intern Med; 153:2389, October 1993.

Ryan EH and Moore WJ: Silicone Breast Implants and Atypical Autoimmune Disease. Annals of Internal Medicine; Vol. 119, No. 10, November 1993.

Nang RN, Sutherland DE, Miller P, and Haburchak DR: Reported Reduction in Sexual Activity after Discovery of HIV Seropositivity in US Soldiers. The Journal of the US Army Medical Department; 1993.

Katial R, Honeycutt W, and Oswald SG: Pneumocystis Carinii Pneumonia Presenting as Focal Bibasilar Uptake on Gallium Scan During Aerosolized Pentamidine Prophylaxis. Journal of Nuc Med; 35(6):1034-1037, Jun 1994.

Whitlock, Lowery and Fine: Sarcoidosis and HIV Infection. Chest; 105:1299, Apr 1994.

Sokol MS, Kavolius J, Schaaf M, and D'Avis: Recurrent Hyperparathyroidism from Benign Neoplastic Seeding: A Review with Recommendations for Management. Surgery 1993; (113):456-461.

Tenholder MF, and Whitlock WL: Is Chest CT Performed Too Often? Chest; 105(2):647-8, Feb 1994.

Garris PD, Sokol MS, Kelly K, Whitman GS, and Plouffe L Jr: Leuprolide Acetate Treatment of catamenial Pneumothorax. Fertility & Sterility; 61(1):173-4, Jan 1994.

Jacobsen LK, Rabinowitz I, Popper MS, Solomon RJ, Sokol MS, and Pfeffer CR: Interviewing Prepubertal Children About Suicidal Ideation and Behavior. Journal of the American Academy of Child & Adolescent Psychiatry; 33(4):439-52, May 1994.

DEPARTMENT OF PATHOLOGY

Romero N, Ranlett RD: Myxoid Malignant Fibrous Histiocytoma. American Society of Clinical Pathologists Check Sample TD 93-4; 1993.

Wilkerson RW, and Sen JK: Intravascular Large Cell Lymphomatosis (Angiotropic Large Cell Lymphoma). American Society of Clinical Pathologists Check Sample TD 93-5 (TD-121); 1993.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Mahadik SP, Wakade CG, Scheffer R, Correnti EE, Borison RL, and Mukherjee S: Abnormal Growth of Skin Fibroblasts from Drug-Naive Psychotic Patients. Biological Psychiatry 1993; 33:69(A).

SOCIAL WORK SERVICE

Longfield JN, Brundage J, Badger G, Vire D, Milazzo M, Ry K, Gemmill R, Magruder C, Oster CN, and Roberts C: Look-Back Investigation after Human Immunodeficiency Virus Seroconversion in a Pediatric Dentist. The Journal of Infection Diseases 1994; 169:1-8.

DEPARTMENT OF SURGERY

General Surgery Service

Flaherty S, and Grishkin BA: Airway Obstruction by Anterior Mediastinal Mass. Successful Management by Percutaneous Aspiration. Chest; Vol. 106, p. 947-948; Sept. 1994.

Cohen AJ, Moore P, Jones C, Miner TJ, Carter WR, Zurcher RP, Lupkas R, and Edwards FH: Effect of Internal Mammary Harvest on Postoperative Pain and Pulmonary Function. Ann. Thorac. Surg.; 56:1107-1109, 1993.

Waddell BE and Martindale RG: The Uterine Sound as a Convenient, Cost-Effective Method for Creating the Subcutaneous Tunnel for Long-Term Venous Catheters. Journal of Parenteral and Enteral Nutrition; 18(1):81-82, 1994.

Waddell BE and Martindale RG: The Uterine Sound as a Convenient, Cost-Effective Method for Creating the Subcutaneous Tunnel for Long-Term Venous Catheters. Journal of Parenteral and Enteral Nutrition; 18(1):81-82, 1994.

Modesto VL, Harkins B, Calton WC, and Martindale RG: Laparoscopic Gastrostomy Using Four-Point Fixation. Amer. J. of Surg.; 167(2): 273-276, Feb. 1994.

Orthopaedic Service

Geissele AE, Ogilvie JW, Cohen K, and Bradford DS: Thoracoplasty for the Treatment of Rib Prominence in Thoracic Scoliosis. Spine; Vol. 19, Number 14, pp. 1636-1642, 1994.

Kirkham B, Popp CA, Transfeldt EE, and Geissele AE: Radiographic Evaluation of Instability in Spondylolisthesis. Spine; Vol. 19, Number 15, pp. 1697-1703, 1994.

Raab, MG: Sideswipe Elbow Fractures. Contemporary Orthopaedics; 1994.

Raab, MG: A Method of Pediatric Short-Army Cast Application. Orthopaedic Review; Volume 23, February 1994.

Raab, MG: Eikenella Corrodens Vertebral Osteomyelitis. Clinical Orthopaedic and Related Research; 293:144-7, 1993.

PRESENTATIONS FY 94

DEPARTMENT OF CLINICAL INVESTIGATION

McPherson JC Jr, Chuang AH, and McPherson JC III: Intravenous Surfactant Treatment Enhancement of Early Wound Healing. Effect of Pre-Treatment, Second Annual Wound Care Symposium, Richmond, Virginia, 23-26 May 1993.

Paustian PW, Akiyama DP, Chuang AH, McPherson JC III, and McPherson JC Jr: Wound Repair and Regeneration, First Joint Meeting of the Wound Healing Society and the European Tissue Repair Society. Amsterdam, The Netherlands, 22-25 August 1993.

Tobias SW, Williams LE, Chuang AH, McPherson JC III, and McPherson JC Jr: Red Blood Cell Deformability During an Alimentary Lipemia, 28th Annual Southeastern Regional Lipid Conference, Cashiens, North Carolina, 20-22 October 1993.

McPherson JC Jr, Prillaman C, Runner RR, and McPherson JC III: Pluronic F-127, a Hyperlipemic Agent, Stimulates Fibroblast Contraction of Collagen Lattices, 28th Annual Southeastern Regional Lipid Conference, Cashiens, North Carolina, 20-22 October 1993.

Williams LE, Chuang AH, McPherson JC III, and McPherson JC Jr: The Effect of a Hyperlipemic Agent, Pluronic F-127, on Red Blood Cell Deformability During the Development of the Lipemic State, 28th Annual Southeastern Regional Lipid Conference, Cashiens, North Carolina, 20-22 October 1993.

Chuang AH, Tobias SW, Williams LE, McPherson JC III, and McPherson JC Jr: Alteration of Red Blood Cell Sedimentation Rate Following Intravenous Administration of a Hyperlipemic Agent (Poloxamer 407), 28th Annual Southeastern Regional Lipid Conference, Cashiens, North Carolina, 20-22 October 1994.

Murray MT, Chuang AH, Runner RR, Paustian PW, McPherson JC III, and McPherson JC Jr: Pluronic F-68 Reduces Post-Burn Edema, The Third Annual Wound Care Symposium, Richmond, Virginia, 10-13 April 1994.

Tobias SW, Chuang AH, Williams LE, McPherson JC III, and McPherson JC Jr: Red Blood Cell Deformability Following a Single Menhaden Oil Meal, Vascular Biology and Medicine Meeting, Houston, Texas, 17-19 April 1994.

Kriegel DL, Jones CD, Runner RR, Black JB, Chuang AH, McPherson JC III, and McPherson JC Jr: "Glass Effect" on Red Blood Cells (RBCs) May Be Affected by Charge As Well As pH, 171st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Ballard JB, Stringer MD, Runner RR, Black JB, Chuang AH, McPherson JC III, and McPherson JC Jr: Anti-Freeze Protein and Rouleau Formation, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Stringer MD, Ballard JB, Chuang AH, Black JB, Runner RR, McPherson JC III, and McPherson JC Jr: Anti-Freeze Protein and the Mechanical Fragility of Rat Red Blood Cells, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Jones CD, Kriegel DL, Chuang AH, Black JB, McPherson JC III, and McPherson JC Jr: Comparison of Red Cell Deformability in Polyvinyl Pyrrolidone and Dextran, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Meyers CE Jr, Chuang AH, Black JB, Runner RR, McPherson JC III, and McPherson JC Jr: 1.9-Dimethylmethylene Blue for Mucin Estimation, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Akiyama DP, Chuang AH, Paustian PW, McPherson JC III, and McPherson JC Jr: 62nd Annual Scientific Meeting of the Southeastern Surgical Congress, Orlando, Florida, April 1994.

McPherson JC Jr, Akiyama DP, Chuang AH, Runner RR, Paustian PW, and McPherson JC III: Pluronic F-127 Enhances Blood Flow and Survival of Elevated Skin Flaps, Southeastern Surgical Congress, 62nd Annual Scientific Meeting, Orlando, Florida, April 1994.

Paustian PW, Prillaman C, Runner RR, McPherson JC III, and McPherson JC Jr: In Vitro Evaluation of Pluronic F-127 Stimulation of Wound Healing Using Collagen Lattice Plates, Third Annual Wound Care Symposium, San Francisco, California, 18-20 May 1994.

Murray MT, Chuang AH, Runner RR, Paustian PW, McPherson JC III, and McPherson JC Jr: Pluronic F-68 Reduces Post-Burn Edema, Third Annual Wound Care Symposium, San Francisco, California, 18-20 May 1994.

Paustian PW, Prillama C, Runner RR, McPherson JC III, and McPherson JC Jr: In-Vitro Evaluation of Pluronic F-127 Stimulation of Wound Healing Using Collagen Lattice Plates, Wound Healing Society Meeting, San Francisco, California, 18-20 May 1994.

McPherson JC Jr, Chuang AH, and McPherson JC III: Second Annual Wound Care Symposium, Richmond, Virginia, 23-26 May 1994.

Akiyama DP, Chuang AH, Paustian JC, McPherson JC III, and McPherson JC Jr: Intravenous Poloxamer 188 Increases Patency of Capillaries in Skin Flaps But Does Not Prevent Contracture of the Flap, 62nd Annual Scientific Meeting of the Southeastern Surgical Congress.

McPherson JC Jr, Akiyama DP, Chuang AH, Runner RR, Paustian PW, and McPherson JC III: Pluronic F-127 Enhances Blood Flow and Survival of Elevated Skin Flaps, 62nd Annual Scientific Meeting of the Southeastern Surgical Congress.

DENTAL ACTIVITY

Czuszak CA, Sutherland DE, and Stein SH: Interleukin-6 Production Due to Endogenous Interleukin-18 and Prostaglandin-E2 in HGFs, 72nd General Session and Exhibition of the International Association for Dental Research, Seattle, Washington, 9-13 March 1994.

Breault LG, Runner RR, Schuster GL, Billman MA, and McPherson JC III: The Effect of an Endodontic Medicament on the Attachment of Gingival Fibroblast to Dentin, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

Tolson GE IV, Singh BB, Billman MA, McPherson JC III, and McPherson JC Jr: Comparison of Pluronic F-68 and Transforming Growth Factor Beta on Incisional Wound Healing, 71st Annual Meeting, Georgia Academy of Science, Kennesaw, Georgia, 29-30 April 1994.

DEPARTMENT OF FAMILY PRACTICE

Epperly TD: Common Eye Urgencies, Community Medicine Conference, Willigen, Germany, 01 November 1993.

Epperly TD: Common Skin Problems, Community Medicine Conference, Willigen, Germany, 02 November 1993.

Epperly TD: Management and Triage of the Radiation Injured Patient, Community Medicine Conference, Willigen, Germany, 03 November 1993.

Epperly TD: Prostate Disease in the 90's, Community Medicine Conference, Willigen, Germany, 02 November 1993.

Trzepkowski K: The Mead Johnson Family Medicine Research Morum, Fort Lauderdale, Florida, 03-05 December 1993.

Reese MM: The USAFP XIX Scientific Assembly, Norfolk, Virginia, 12-19 March 1994.

Derese TS: The USAFP XIX Scientific Assembly, Norfolk, Virginia, 12-19 March 1994.

Littell JT: The USAFP XIX Scientific Assembly, Norfolk, Virginia, 12-19 March 1994.
Phelps K: The Cognitive Skills Required to do Clinical Diagnosis, The USAFP XIX Scientific Assembly, Norfolk, Virginia, 12-19 March 1994.

Epperly TD: Stroke - What's New, Uniformed Services Academy of Family Practice 19th Scientific Assembly, Norfolk, Virginia, 18 March 1994.

Epperly TD: Common Eye Urgencies, Department of State Foreign Service Medical Officers Meeting, Bethesda, Maryland, 6 April 1994.

Epperly TD: Common Eye Urgencies, 45th Military Medical Surgical Clinical Congress, Willingen, Germany, 18 April 1994.

Epperly TD: The Ten Best Articles for Primary Care Docs in the Last 18 Months, 45th Military Medical Surgical Clinical Congress, Willingen, Germany, 18 April 1994.

Epperly TD: Office Dermatology, 45th Military Medical Surgical Clinical Congress, Willingen, Germany, 19 April 1994.

Epperly TD: How to Diagnose and Manage Breast Lumps, 45th Military Medical Surgical Clinical Congress, Willingen, Germany, 20 April 1994.

Epperly TD: BPH, Prostate Cancer, PSA, and You, 45th Military Medical Surgical Clinical Congress, Willingen, Germany, 20 April 1994.

Epperly TD: Office Dermatology, Capital Conference: A Family Practice Review, Andrews Air Force Base, Maryland, 23 May 1994.

Epperly TD: What's New with CVA's/TIA's, Capital Conference: A Family Practice Review, Andrews Air Force Base, Maryland, 25 May 1994.

Gambrell R: Clinical Abstract, American College of Sports Medicine Annual Meeting, Indianapolis, Indiana, 31 May-06 June 1994.

DEPARTMENT OF MEDICINE

Young CR and Whitlock WL: Diaphragmatic Myoclonus, 59th Annual International Scientific Assembly, American College of Chest Physicians, Orlando, Florida, 24-28 October 1993.

Hilburn RB and Whitlock WL: Improved Metered-Dose Inhaler Technique, 59th Annual International Scientific Assembly, American College of Chest Physicians, Orlando, Florida, 24-28 October 1993.

Young CR, and Whitlock WL: Tenth Annual Scientific Meeting of the American College of Physicians, Orlando, Florida, 18-21 November 1993.

Doers JT: Tenth Annual Scientific Meeting of the American College of Physicians, Orlando, Florida, 18-21 November 1993.

Wehner JH, Kirsch CM, Jensen WA, Kagawa FT, Campagna AC, and Whitlock WL: Exercise Capacity During Internship, 1994 ALA/ATS International Conference, Boston, Massachusetts, 21-25 May 1994.

Hammerschlag MR, Roblin PM, Cassell G, Hahn D, Puopolo A, Walker B, Westmerman J, and Whitlock WL: Microbiologic Efficacy of Azithromycin for the Treatment of Community-Acquired Lower Respiratory Tract Infection Due to Chlamydia Pneumoniae. The 2nd Annual International Conference on the Macroliade Azalides and Streptogramins, January 1994.

DEPARTMENT OF NURSING

Kujala E: 5th National Conference on Nursing Administration Research, Chapel Hill, North Carolina, 20-22 October 1993.

DEPARTMENT OF PATHOLOGY

Shikle JF: Wegener's Granulomatosis, Quarterly Meeting Augusta Regional Society of Pathologists, Augusta, Georgia, 28 October 1993.

Shikle JF: Lepromatous Leprosy, Quarterly Meeting Augusta Regional Society of Pathologists, Augusta, Georgia, 28 October 1993.

Wozniak A, Benton FR, Goodhue WW, Thomas DE, and Brewer PD: Seroprevalence of Hepatitis B Virus Infection in a US Army Blood Donor Population, and Hepatitis B Surface Antigen Testing, Society of Armed Forces Medical Laboratory Scientists Eighteenth Annual Meeting, Reno, Nevada, 13-17 March 1994.

White JC, Kozar MP, Koziateck VP, and O'Quinn GC: US Army Blood Lead Program Update, Society of Armed Forces Medical Laboratory Scientists 18th Annual Meeting, Reno, Nevada, 13-17 March 1994.

Wozniak A, Benton FR, Goodhue WW, Thomas DE, and Brewer PD: Seroprevalence of Hepatitis B Virus Infection in a US Army Blood Donor Population, and Hepatitis B Surface Antigen Testing, Medical College of Georgia Eighteenth Annual Postgraduate Pathology Symposium, Augusta, Georgia, 23-24 April 1994.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Mahadik SP, Wakade CG, Scheffer R, Correnti E, Borison RL, and Mukherjee S: Abnormal Growth of Skin Fibroblasts from Drug=Naive Psychotic Patients, Annual Meeting of the Socity of Biological Psychiatry, San Francisco, California, 1993.

Mukherjee S, Scheffer R, Correnti EE, Wakade CG, Borison RL, and Mahadik SP; Fibroblast Studies in First-Episode Phychoses, Annual Meeting of the American Psychiatric Association, San Francisco, California, 1993.

Scheffer, R, Correnti EE, Costa R, and Mukherjee S: Neurogical Signs at the Onset of Psychosis, Annual Meeting of the American Psychiatric Association, San Francisco, California, 1993.

Kelkar H, Scheffer R, Correnti EE, Mukherjee S, and Kahadik SP: Anti-Oxidant Enzyme Defense System is Altered in Erythrocytes from Drug-Naive, First-Episode Schizophreniform Patients, Annual Meeting of the Society of Neuroscience, Washington, DC, 1993.

Logan WE: A Brief Introduction of Medical Ethics, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 04 Feb 1993.

Ryder GC: Chronic Illness, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 18 Feb 1993.

Ryder GC: Aviation Psychiatry and Alcoholism in Aviation, Flight Surgeons Course, Fort Rucker, Alabama, 04 Mar 1993.

Ryder GC: Update on Psychiatry and Alcoholism, Operational Aeromedical Problems Course, 24 Mar 1993.

Correnti LM: Psychotherapy Outcome Research, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 21 Oct 1993.

Perez IJ: Antidepressants - Effects on Sexual Function, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 14 Jan 1993.

Correnti LM: Computer Assisted Documentation of Training in Psychiatry, , Workshop Leader, 1994 American Association of Directors of Psychiatric Residency Training Annual Meeting, Jan 1994.

Perez IJ: Psycho-Jeopardy, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georiga, 20 Jan 1994.

Ryder GC: Aviation Psychiatry and Alcohol, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 27 Jan 1994.

Correnti LM: Residency Training Update, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 17 Feb 1994.

Mackey JF: The American Society for Psychosomatic Obstetrics and Gynecology, San Diego, California, 24-27 February 1994.

Correnti LM: The Family Practice/Psychiatry Co-Clinic - Review of a Two Year Experience, Free University Presentation, 1994 Association for Academic Psychiatry Annual Meeting, Mar 1994.

Correnti LM: The Family Practice/Psychiatry Co-Clinic - Review of a Two Year Experience, Medical College of Georgia Department of Psychiatry Grand Rounds, Augusta, Georgia, 10 Mar 1994.

Correnti EE: Postpartum Psychiatric Disorders, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 10 Mar 1994.

Correnti LM: The Relationship of Menstrual Cycle Phase to Acute Presentation for Psychiatric Treatment, 1994 Army Psychiatry Conference, San Antonio, Texas, Apr 1994.

Logan WE: Informed Consent, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 31 March 1994.

Mukherjee S, Mahadik SP, Horrobin DF, Jenkins K, Correnti EE, and Scheffer R: Membrane Fatty Acid Composition of Fibroblasts from Schizophrenic Patients, Annual Meeting of the Society of Biologicl Psychiatry, Philadelphia, Pennsylvania, 18-22 May 1994.

Mukherjee S, Mahadik SP, Correnti EE, and Scheffer R: The Anti-Oxidant Defense System at the Onset of Pyschosis, Annual Meeting of the Society of Biological Psychiatry, Philadelphia, Pennsylvania, 18-22 May 1994.

Scheffer R, Correnti EE, Borison RL, and Mukherjee S: Premorbid History and Clinical Manifestations at the Onset of Psychosis, Annual Meeting of the Society of Biological Psychiatry, Philadelphia, Pennsylvania, 18-22 May 1994.

Scheffer R, Correnti EE, Borison RL and Mukherjee S: Temporal Stability of Neurological Signs in the First-Episode Psychotic Patients, Annual Meeting of the Society of Biological Psychiatry, Philadelphia, Pennsylvania, 18-22 May 1994.

Scheffer R. Diamond BI, Borison RL, Correnti EE, and Mukherjee S: Low Plasma Homovanillic Acid (HVA) at the Onset of Psychosis, Annula Meeting of the Society of Biological Psychiatry, Philadelphia, Pennsylvania, 18-22 May 1994.

Scheffer R, Diamond BI, Borison RL, Correnti EE, and Mukherjee S: Platelet 3H Imipramine Binding at the Onset of Psychosis, Annual Meeting of the American Psychiatric Association, Philadelphia, Pennsylvania, 18-22 May 1994.

Scheffer R, Correnti EE, and Mukherjee S: Neuroleptic Response Very Early in Schizophrenia, Annual Meeting of the American Psychiatric Association, Philadelphia, Pennsylvania, 18-22 May 1994.

Perez IJ: Second Annual Psycho-Jeopardy, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 01 Sep 1994.

Ryder GC: The Flight Surgeon and the Psychiatrist, Department of Psychiatry Grand Rounds, EAMC, Fort Gordon, Georgia, 08 Sep 1994.

Sheehan TD: Complexity and Neural Network Theory, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 15 Sep 1994.

Fosmire DP: Movement Disorders, Department of Psychiatry and Neurology Grand Rounds, EAMC, Fort Gordon, Georgia, 22 Sep 1994.

DEPARTMENT OF SURGERY

General Surgery Service

Mulligan CR: The Southeast Surgical Congress 62nd Annual Scientific Meeting, Lake Buena Vista, Florida, 06-11 Feb 1994.

Taylor RB: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Chapman DC: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Workman CR: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Dinsmore RC: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Harkins MB: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Miller SK: The American College of Surgeons, Georgia Chapter Meeting, Sea Island, Georgia, 10-14 March 1994.

Pack MS: The 47th Annual Cancer Symposium, Houston, Texas, 16-21 March 1994.

Taylor T, Lepage P, and Modesto V: Laparoscopic Appendectomy versus Open Appendectomy at Eisenhower Army Medical Center, Gary P. Wratten Surgical Symposium. Cloudcraft, New Mexico, April 1994.

Orthopaedic Service

Raab MG: Postoperative Toxic Shock Syndrome, Eastern Orthopaedic Association, Orlando, Floria, October 1993.

Raab MG: Postoperative Toxic Shock Syndrome, Infectious Disease Society of America, New Orleans, Louisiana, October 1993.

Erpelding JM: Core Decompression and Fibular Strut Grafting for Femoral Avascular Necrosis: A Series Review, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Erpelding JM: Strength, Weight and Cost Comparison of Available Unit External Fixators, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Erpelding JM: Biomechanical Analysis of Fibular Fixation vs Plate and Screw Fixation, Preliminary Results, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Arthroscopic Shoulder Stabilization for Acute, Initial Anterior Dislocation Using a Bioabsorbable Tack, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Prevention of Immobilization-Induced Strength Loss by Administration of an Anabolic-Androgenic Steroid, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Recurrent Instability After Open Shoulder Reconstruction in Athletes, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Arthroscopic Assisted Anterior Cruciate Ligament Reconstruction: Comparison of Endoscopic with the Two Incision Technique, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Effects of Postmortem Freezing on Passive Properties of Rabbit Digitorum Longus Muscle Tendon Complex, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

Taylor DC: Impact of an Outside-the-Boot Ankle Brace on Sprains Associated with Military Airborne Training, Orthopaedic Research Society, New Orleans, Louisiana, February 1994.

Taylor DC: Effects of Postmortem Freezing on Passive Properties of Rabbit Digitorum Longus Muscle Tendon Comples, Orthopaedic Research Society, New Orleans, Louisiana, February 1994.

TRANSITIONAL

Pope R, Popovic N, McKinney L, and Berrey B: The Effect of Extracorporeal Shock Waves on the Compartment Pressures in the Rabbit Leg, Society of Military Orthopaedic Surgeons, Bethesda, Maryland, December 1993.

PRESENTATIONS

Orthopaedic Service

Taylor DC: Prevention of Immobilization-Induced Strength Loss by Administration of an Anabolic-Androgenic Steroid (Poster), Orthopaedic Research Society, New Orleans, Louisiana, February 1994.

Taylor DC: Recurrent Instability After Open Shoulder Reconstruction in Athletes, American Academy of Orthopaedics, New Orleans, Louisiana, February 1994.

Taylor DC: Arthroscopic Shoulder Stabilization for Acute, Initial Anterior Dislocation, Americam Academy of Orthopaedics, New Orleans, Louisiana, February 1994.

Taylor DC: Arthroscopic Bioabsorbable Tack Stabilization of Initial Anterior Shoulder Dislocations: A Preliminary Report, Arthroscopy Association of North America, April 1994.

Taylor DC: Interscalene Anesthesia for Shoulder Arthroscopy in a Community Hospital, Arthroscopy Association of North America, April 1994.

Taylor DC: An Anabolic-Androgenic Steroid Limits Immobilization-Induced Atrophy in a Rabbit Model, Meeting of the Piedmont Orthopaedic Society, May 1994.

Harrington G: Complications of External Fixation of Femur Fractures, Children's Orthopaedic Day, Denver, Colorado, May 1994.

PUBLICATIONS

Department of Nursing

Anderson FD, Cunningham SG, and Maloney JP: Indirect Blood Pressure Measurement: A Need to Reasses., American Journal of Critical Care, Vol. 2, Number 4, pp. 272-277.

Anderson FD, Maloney JP, and Redland AR: Study of Hope in Patients with Critical Burn Injuries., Journal of Burn Care and Rehabilitation, Vol. 14, Number 2, Part 1.

ABSTRACTS FY 94

DEPARTMENT OF CLINICAL INVESTIGATION

Akiyama DP, Chuang AH, Paustina PW, McPherson JC III, and McPherson JC Jr: Intravenous Poloxamer 188 Increase Patency of Capillaries in Skin Flaps But Does Not Prevent Contracture of the Flap.

Murray MT, Chuang AH, Runner RR, Paustian PW, McPherson JC III, and McPherson JC Jr: Pluronic F-68 Reduces Post-Burn Edema.

Tobias SW, Chuang AH, Williams LE, McPherson JC III, and McPherson JC Jr: Red Blood Cell Deformability Following a Single Menhaden Oil Meal.

McPherson JC Jr, Chuang AH, and McPherson JC III: Intravenous Surfactant Treatment Enhancement of Early Wound Healing. Effect of Pre-Treatment.

Craft DW, Williams LE, Kozar MP, Thomas EE, and Forney JR: Out of the Ivory Tower: Evaluation of Rapid Diagnostic Human Immunodefiency Virus (HIV) Test Kits in a Filed Environment.

Paustian PW, Akiyama DP, Chuang AH, McPherson JC III, and McPherson JC Jr: Wound Repair and Regeneration.

Tobias SW, Chuang AH, Williams LE, McPherson JC Jr, and McPherson JC III: Omega-3 Fatty Acids in Nutrition, Vascular Biology and Medicine.

McPherson JC Jr, Chuang AH, and McPherson JC III: Second Annual Wound Care Symposium.

Paustian PW, Chuang AH, McPherson JC III, Runner RR, Fitzpatrick BD, Shahan MH, Plowman KM, and McPherson JC Jr: Early Wound Healing Enhancement and Edema Control by a New Class of Compounds.

Paustian PW, Prillaman C, Runner RR, McPherson JC III, and McPherson JC Jr: In-Vitro Evaluation of Pluronic F-127 Stimulation of Wound Healing Using Collagen Lattice Plates.

Meyers CE Jr, Chuang AH, Black JB, Runner RR, McPherson JC III, and McPherson JC Jr: 1.9-Dimethylmethylene Blue for Mucin Estimation.

DENTAL ACTIVITY

Bisch F: The Effects of Cold Storage on Osteoblast Viability and Interleukin-6 (IL-6) Production in Murine Bone Cell Culture.

Breault LG: The Effects of Intracanal Medicaments on Fibroblast Attachment to Dentin Surfaces.

Parker JE, Gaston ML, Adrian ED, Runyan DA, and Gardner FM: A Comparison of Luting Cements for the CeraOne Abutment System.

Luzader JL, Primack PD, and Loushine RJ: Prevention of Coronal Canal Leakage Following Non-Vital Bleaching.

Armstrong TF, Primack PD, and Loushine RJ: A Comparison of Class I Root Preparation Techniques.

Woollard GW, Rueggeberg FA, Primack PD, Loushine RJ, and Horner JA: SEM Evaluation of the Rispisonic Files after Repeated Use.

Woollard GW, Rueggeberg FA, Primack PD, Loushine RJ, and Anderson RW: Wear and Cutting Efficiency of the Rispisonic File.

Yoshiyama M, Carvalho RM, Horner JA, and Pashley DH: Total Etch Dentin Bonding Evaluated Using a Reverse-Sandwich Technique.

Breault LG, Runner RR, Schuster GL, Billman MA, and McPherson JC III: The Effect of an Endodontic Medicament on the Attachment of Gingival Fibroblast to Dentin.

Bisch FC, Hanson BS, Best NH, Tobias SW, and Craft DW: Production and Detection of Interleukin-6 (IL-6) and Tumor Necrosis Fractor-Alpha (TNF-a) in Murine Bone Cell Culture.

Tolson GE IV, Singh BB, Billman MA, McPherson JC III, and McPherson JC Jr: Comparison of Pluronic F-68 and Transforming Growth Factor Beta on Incisional Wound Healing.

DEPARTMENT OF MEDICINE

Whitlock WL: Microbiologic Efficacy of Azithromycin for the Treatment of Community-Acquired Lower Respiratory Tract Infection Due to Chlamydia pneumoniae.

Wehner JH, Kirsch CM, Jensen WA, Kagawa FT, Campagna AC, and Whitlock WL: Exercise Capacity During Internship.

Hilburn RB, Bookstaver D, and Whitlock WL: Angiotensin-Converting Enzyme Inhibitor Hepatotoxicity: Further Insights.

Stafford CT, Wise SL, Robinson DA, Crosby BL, and Hoffman DR: Safety and Efficacy of Fire Ant Venom in the Diagnosis of Fire Ant Allergy.

Hammerschlag MR, Roblin PM, Cassell G, Hahn D, Puopolo A, Walker B, Westerman J, and Whitlock WL: Microbiologic Efficacy of Azithromycin for the Treatment of Community-Acquired Lower Respiratory Tract Infection Due to Chlamydia Pneumoniae.

DEPARTMENT OF PATHOLOGY

Wozniak A, Benton FR, Goodhue WW, Thomas DE, and Brewer PD: Seroprevalence of Hepatitis B Virus Infection in a US Army Blood Donor Population, and Hepatitis B Surface Antigen Testing, Armed Forces Medical Laboratory Scientists 18th Annual Meeting, Reno, Nevada, 13-17 March 1994.

White JC, Kozar MP, Koziatek VP, and O'Quinn GC: US Army Blood Lead Program Update, Society of Armed Forces Medical Laboratory Scientists 18th Annual Meeting, Reno, Nevada, 13-17 March 1994.

Wozniak A, Benton FR, Goodhue WW, Thomas DE, and Brewer PD: Seroprevalance of Hepatitis B Virus Infection in a US Army Blood Donor Population, and Hepatitis B Surface Antigen Testing, Medical College of Georgia 8th Annual Postgraduate Pathology Symposium, Augusta, Georgia, 23 - 23 April 1994.

Wozniak A, Goodhue WW, Benton FR, Green J, and Brewer PD: The Correlation of Acid Fast Bacteria (AFB) Direct Exam Smears with AFB Cultures Using Sputa from Undiagnosed Patients, 94th General Meeting of American Society for Microbiology, Las Vegas, Nevada, 23-27 May 1994.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Mahadik SP, Mukherjee S, Correnti EE, Kelkar HR, Wakade CG, Costa RM, and Scheffer R: Plasma Membrane Phospholipid and Cholestrol Distribution of Skin Fibroblasts from Drug-Naive Patients at the Onset of Psychosis.

DETAIL

SUMMARY

SHEETS

DETAIL SUMMARY SHEET

Date: 28 Oct 93	**Protocol** 87-16	**Status** Terminate	
Title: The Utility of the 60-kilodalton Oncofetal Tumor Marker in the Monitoring of Treatment of Cancer Patients			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Donald E. Sutherland, PhD, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation, Surgery		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 92, Jan 93, & Oct 93 Continue	

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

Number of Subjects Enrolled: 74

Progress: All patients tested to date have shown a dramatic drop in OFP followup treatment to include no evidence of OFP at long term followup.

Problems Encountered: Time limitations and inability to get fresh radiolabeled acetic acid kept this project from being completed.

DETAIL SUMMARY SHEET

Date: 28 Oct 93	**Protocol** 87-40	**Status** Ongoing	
Title: Pathology Applications of X-ray Spectrometric Microanalysis			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jack A. Horner, BS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation/Pathology		**Associate Investigators:** Phyllis Brewer, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94 Continue	

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Progress: Sixteen additional samples were added to the data base. The use of these techniques for blood/lead determinations will be investigated in the near future. Suitable reference standards are being planned and prepared.

DETAIL SUMMARY SHEET

Date: 28 Oct 93 **Protocol** 89-38 **Status** Ongoing	
Title: Non-ionic Surfactants in the Treatment of Third Degree Burns in Rats	
Start Date: Jul 89	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	
Key Words: Surfactant Burn treatment	**Associate Investigators:** James C. McPherson, Jr., MD COL Kent M. Plowman, MC Paul W. Paustian, MD Royce R. Runner, MT (ASCP) MAJ R. R. Haase, MC
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 93, Oct 94 Continue

Study Objective: To study potential protective effects on non-ionic surfactants in the treatment of third degree burns.

Technical Approach: Effect of single and multiple doses of non-ionic surfactants given IV thirty minutes following a full thickness burn will be studied to evaluate burn wound healing.

Progress: Continue to evaluate pluronic polyols in third degree burns using various doses and administration techniques. This protocol has resulted in two published papers, a presentation at the Army Science Conference, and several presentations at scientific meetings this FY.

Problems Encountered: Histologic evaluations are difficult to obtain due to lack of appropriate trained personnel.

DETAIL SUMMARY SHEET

Date: 28 Oct 93 **Protocol** 91-18 **Status** Completed	
Title: Effects of Different Methods of Hair Removal on the Measurement of Skin Blood Flow in the Rat Using a Doppler Laser Blood Perfusion Monitor and the Effect of Elevated Body Core Temperature on Skin Blood Flow	
Start Date: Dec 90	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	
Key Words: Blood flow	**Associate Investigators:** A. Henry Chuang, PhD Royce R. Runner, ASCP Paul W. Paustian, MD James C. McPherson, Jr, MD
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 93 Continue

Study Objective: To determine the best method for hair removal from a rat in order to accurately measure blood flow and to determine if skin blood flow is altered by increasing the body core temperature.

Technical Approach: Hair will be removed by clipping (current method), surgical clipping, wet shaving or chemical removal. Skin blood flow will be measured using a Doppler laser flow technique. Increased body core temperature effect on skin blood flow will be measured.

Progress: Blood flow in the skin of a fur covered animal has been successfully measured by fur removal techniques developed using this protocol. Results have lead to successful results on one resident research protocol resulting in several presentations and one manuscript is ready for submission.

Problems Encountered: Hair removal from the skin without abrasion or chemical burn to the skin.

DETAIL SUMMARY SHEET

Date:	28 Oct 93 **Protocol** 91-19		**Status** Ongoing
Title:	Development of a Heat Stroke Model in the Rat and Treatment with Pluronic Polyols		
Start Date:	Jan 91	**Est. Compl. Date:**	Jan 93
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** A. Henry Chuang, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Heat stroke, Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93, Oct 94 Continue	

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters, will require less time to develop and will control the biological variation in the model. It will also study the effect of treatment of two pluronic polyols versus saline as the resuscitative fluid in heatstroke victims (in this case rats).

Technical Approach: Fur will be removed from the rat and the rat allowed to swim in a heated water bath. Pluronic polyol solutions or saline will be administered as resuscitative fluids. The pluronic polyols have been shown by investigators in this laboratory to have membrane protective properties and have been proposed for use as resuscitative agents.

Progress: Initial pilot project begun. Protocol rewritten as DOD Women's Health Care Issue.

DETAIL SUMMARY SHEET

Date: 28 Oct 93	**Protocol** 91-24	Status Terminated	
Title: Derivation and Characterization of Human Periodontal Ligament Fibroblasts			
Start Date: Jan 91		**Est. Compl. Date:**	
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce R. Runner LTC Thomas E. VanDyke, DE	
Key Words: Periodontal ligament Tissue culture			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To establish human periodontal ligament fibroblasts in tissue culture, characterize the cells and investigate differences between human periodontal ligament fibroblasts and human gingival fibroblasts.

Technical Approach: Fibroblast-like cells will be removed from freshly extracted teeth containing the periodontal ligament and grown in tissue culture using techniques specifically developed to isolate and grow the periodontal ligament fibroblasts.

Progress: No progress. There has been a change in emphasis for research projects in periodontics with new staff.

DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 91-37 **Status** Ongoing			
Title: The Effect of Pluronic Polyols on Experimental Edema Produced by Various Means: Arachidonic Acid, Carrageenin, Histamine and Thermal Injury. A Study in Rats and Mice.			
Start Date: Jan 91		**Est. Compl. Date:** Jan 93	
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce R. Runner, ASCP A. Henry Chaung, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Edema Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93, Oct 94 Continue	

Study Objective: Previous investigations in this laboratory supported decreased skin edema in third degree burns. In this study we will investigate both pre- and post-injury IV administration of pluronic polyols on ear, skin and paw edema.

Technical Approach: Ear edema will be produced by topical application of the edema causing agents. Paw edema will be produced by injection of the edema causing agents into the foot pad or by thermal injury. Intradermal and topical applications of these agents will be used on the skin. Both pre- and post-injury IV administration of pluronic polyols will be utilized. Edema formation will be measured over time using a fluid displacement method for the paw and a micrometer caliper for the ear.

Progress: Rat paw edema induced by a thermal injury has been treated with two pluronic polyols. A portion of this data was presented at the 3rd Annual Wound Care Symposium in Richmond, Virginia by one of the participating residents.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 91-74	**Status** Completed	
Title: The Effect of Etidronate in the Treatment of Acute/Chronic Osteomyelitis in the Rat Tibial Model			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ David W. Craft, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation/Pathology		**Associate Investigators:** MAJ Donald E. Sutherland, PhD, MS LTC Tu H. Nguyen, MC Norma Best, DAC T.B. Buxton, PhD Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 91, Oct 94, Continue	

Objective: To investigate the effect of etidronate in the treatment of staphylococcal acute/chronic osteomyelitis in an experimental model.

Technical Approach: Animal model studies are complete. Analysis of bone by radiography and tensile strength is pending.

Progress: Attempts have been made to standardize radiological interpretation by digitized images. If methods are developed for support of continuing research, a new protocol will be submitted.

Problems Encountered: Current software on densitometer is not completely configured to support identification of osteomyelitic lesions on radiographs.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-15		**Status** Ongoing
Title:	Cell Membranes and the Gastric Mucosa from Sodium Fluoride in the Rat		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James C. McPherson III, PhD Royce R. Runner James C. McPherson, Jr., MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93, Oct 94 Continue	

Objective: To investigate the effects of fluoride ion on red blood cells and the gastric mucosa in the rat. Also to evaluate the effects of pluronic polyols when the red blood cells and the rats are treated with sodium fluoride.

Technical Approach: Fresh heparinized rat red blood cells will be incubated in buffered isotonic sodium chloride and sodium fluoride solutions with or without the presence of pluronic polyol, F-68. At various time intervals the percent of hemolysis of red blood cells will be determined. Sodium fluoride solutions will be administered orally to the rats. The stomach and small intestine from the rats treated orally or IV with pluronic polyol, F-127 will be compared with those without F-127.

Progress: The results of the histological study clearly show an effective protection of Omeprezole on the stomach mucosa under toxic level of sodium fluoride.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 92-53	**Status** Terminated
Title:	A Study of p53 in the Plasma of Patients in Stages II - VI of Human Immunodeficiency Virus (HIV-1) Infection		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Donald E. Sutherland, PhD, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation/Medicine		**Associate Investigators:** COL Daniel B. Craig, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine if p53 appears and/or increases in the plasma of HIV-seropositive patients in stages II through VI of the disease.

Technical Approach: Plasma specimens will be drawn from HIV-positive patients in Stages II-VI of the disease and tested for mutant p53 protein by a specific ELISA technique. Patients who progress to a higher level may be asked for additional samples.

Subjects enrolled to date: 19

Problems Encountered: Precision problems encountered with ELISA kit. Unable to get duplicates or repeats or match.

Progress: Nineteen subjects have been enrolled in 5 stages of HIV infection. All tested in duplicate with p53 ELISA. No apparent pattern evolved in stage vs. p53 level.

DETAIL SUMMARY SHEET

Date: 12 Aug 93	**Protocol** 93-59	**Status** Complete	
Title: The Use of Rapid Diagnostic Human Immunodeficiency Virus (HIV) Test Kits in a Field Environment.			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ David W. Craft, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** MAJ John R. Forney, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the sensitivity, specificity, precision, and accuracy of commercially available rapid HIV test kits versus reference methods; the ease of use and interpretation of results; and the shelf life and practicality of storage in a harsh environment.

Technical Approach: A total of 200 human sera will be used in the study. The sera will be acquired from the Department of Pathology, DDEAMC. These sera will be left over from previously ordered test specimens and will not require another specimen collection. At least 100 will be seronegative for HIV and at least 20 will be seropositive for HIV. A few HIV indeterminant sera will also be tested, depending upon availability, not to exceed 10% of the total. A commercially procured HIV seroconversion panel will also be tested in order to facilitate sensitivity studies.

Progress: Field testing complete. Study showed that rapid diagnostic kits for serological evaluation of HIV antibody are available and clinically accurate. These rapid kits can be deployed and used in a DEPMEDS facility. Results presented to Society of Armed Forces Medical Laboratory Scientists in February 1994 and manuscript is currently being prepared.

DETAIL SUMMARY SHEET

Date: 09 Dec 93	**Protocol** 94-33	**Status** Ongoing	
Title: Endogenous Lipemia and Chemo Prevention in Breast Cancer			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James McPherson, III James McPherson, Jr. B.B. Single, MCG	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To be a conducive physiological/biochemical condition to mammary tumorigenesis.

Technical Approach: A rodent model will be used to answer if hyperlipemia caused either by intake of HFD or induced endogenously by surfactants, TWR1339 or pluronic F-127, is a possible causal factor of mammary tumors.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	09 Dec 93 **Protocol** 94-34		**Status** Ongoing
Title:	Breast Cancer Gene Therapy: Transferring Tumor Suppressor Genes into Cancer Cell in-vitro and in-vivo with Viral Carrier Vector (Rats and Mice)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Charles Cheng, MCG		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James McPherson, III, PhD A. Henry Chuang Antonio Milici, MCG	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To establish the parameters needed for tumor suppressor genes to establish the parameters needed for tumor suppressor genes P53 and RB to inhibit the action of oncogenes in vitro and in vivo.

Technical Approach: Phase I: establish a working model with transformed mammary cells in culture to assess the tumor suppressing action of P53 and RB. Phase II: find an efficient retro-viral carrier system to deliver these genes to the host tumor tissues; and Phase III: deliver tumor suppressor genes P53 and RB by retroviral vectors into tumor bearing transgenic mice or syngenic rat.

Subjects enrolled to date:

Problems Encountered:
Progress: Nineteen subjects have been enrolled in 5 stages of HIV infection. All tested in duplicate with p53 ELISA. No apparent pattern evolved in stage vs. p53 level.

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol** 94-50	**Status** Ongoing
Title:	The Effect of Levonorgestrel (Norplant) on the Immune Regulation of Bone Morphogensis in Calverial Cultures from the Laboratory Mouse (Mus Musculus)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ David W. Craft, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Henry Chuang, PhD LTC Him W. Strider, DE LTC Benjamin S. Hanson, DE MAJ Steven W. Tobias, DVM Norma H. Best, BS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To study the incidence of post-operative localized osteitis due to molar extraction in female soldiers using NORPLANT for birth control.

Technical Approach: Propose to study the immune regulatory effect of levonorgestrel on cultured cells involved in bone morphogenesis. The study will move the lab close to being able to grow the cells in continuous culture and reduce the future need for animals for certain bone studies.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 14 Apr 94 **Protocol** 94-51 **Status** Ongoing	
Title: Women's Health Care Issues: Heatstroke in Rattus Norvegicus	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson, III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	**Associate Investigators:** A. Henry Chuang, PhD Royce Runner, Medical Technologist James C. McPherson, Jr., M.D. MAJ Steven Tobias, VC PFC Demetrius Collins, Vet Technician
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 94, Continue

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters and will control for the biological variation in the animal model. Will also study the effect of treatment of two poloxamers versus saline as the resuscitative fluid in heatstroke victims (rats).

Technical Approach: A therapeutic intervention is proposed using poloxamers, compounds that have been shown to protect the red blood cell membrane and decrease interstitial edema in burns. In addition to normal female rats, additional female rats will have their hormonal states altered to access the effects of hormones on heatstroke. This model can be utilized to study various pharmacological and biochemical parameters and functions concurrently.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	14 Apr 94 **Protocol** 94-52		**Status** Ongoing
Title:	The Application of Non-ionic Surfactants to Wound Healing and Inflammatory States in the Diabetic Animal (Rates: Rattus Norvegicus and Mice: (Mus Musculus)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James C. McPherson, III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce Runner, Medical Technologist James C. McPherson, Jr., M.D. MAJ Steven Tobias, VC PFC Demetrius Collins, Vet Technician	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To determine if administration of poloxamders 188 or 407 will improve the rate of early wound healing in diabetic animals, both animals with chemically induced diabetes and animals which have genetic diabetes.

Technical Approach: Will compare wound healing in all types of injuries proposed in untreated alloxan diabetic rats (controls) and streptozotocin diabetic rats (controls).

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	14 Apr 94 **Protocol** 94-53		**Status** Ongoing
Title:	Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Steven W. Tobias, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** COL James Elmore, DVM	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation and Veterinary Services, using government owned animals.

Technical Approach: Use colony animals only for procedures which do not require euthanasia. A variety of animal use protocols require that the personnel providing this support have some measure of proficiency and competency in the performance of tasks associated with conducting these studies. It is necessary for personnel to learn new tasks, new methods, new procedures, or combinations thereof. It is necessary for personnel to practice skills which they already possess to establish a means for utilizing available animal resources to obtain this required training.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol** 94-54	**Status** Ongoing
Title:	Measurement of Calcium/Bone Loss Under Stressful Conditions in Female Soldiers During Deployment Utilizing Rattus Norvegicus as a Model		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James C. McPherson, III, PhD Royce Runner, Medical Technologist James C. McPherson, Jr., M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To investigate the bone strength and bone calcium in female rats subjected to various stresses (physical exercise, heat, electric shock and noise) to mimic certain stressful conditions which the female soldier may encounter during deployment.

Technical Approach: In part I of this study on the measurement of calcium and bone loss under stressful conditions in females, will investigate the changes of calcium content in bone, bone strength and bone density in young adult male and female rats under various stressors at different intensities and through different durations.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	12 May 94	**Protocol** 94-59	**Status** Ongoing
Title:	A New In Vitro Model Using Laboratory Mouse (Mus Musculus) Osseous Cells and An In Vivo Animal Model (Rattus Norvegicus) for Evaluating Biocompatability and Cytotoxicity of Dental Impression Materials		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Dennis A. Runyan, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** LTC Benjamin S. Hanson, DE LTC Stephen M. Cameron, DE COL David M. Lewis, DE MAJ David W. Craft, MS MAJ Steven W. Tobias, MS, DVM	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To investigate the biocompatibility and cytotoxicity of several dental polymeric impression materials, including three different polyvinylsiloxanes, a polyether, and a polysulfide rubber.

Technical Approach: This study will focus on the effects on osteoblasts and bone. All animals in each group will be randomly selected. Which holes are unfilled or filled will be arrived at by random selection. This manner will allow confound location as a potential extraneous factor. Rats will be administered tetracycline immediately post-operatively to mark the bone levels at the time of surgery. Rats will be allowed to heal for 120 days on normal diets. The mouse fetal osteoclasts will be harvested for use in cell culture. Post-operative pain will be monitored by behavioral criteria with analgesics administered required.

Subjects enrolled to date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 91-9 **Status** Complete	
Title: Wear and Cutting Efficiency of Sonic Files	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Leander Lanier Sr, DC	**Facility:** Eisenhower Army Medical Center
Department/Service: Dental Activity/Endodontics	**Associate Investigators:** COL James C. Kulild, DE LTC Patrice D. Primack, DE Jack A. Horner, DAC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Study Objective: To evaluate the wear of Shaper-sonic files after use *in vitro* in a simulated root canal in bovine bone and relate this wear to its cutting efficiency.

Technical Approach: Simulated root canals will be prepared from a single bovine femur. Forty-five specimens will be prepared 3x2x2 cm using a band saw. Three pilot holes, simulating artificial root canals, will be drilled along the 3 cm side of each block through the cortical plate completely through the 2 cm side. Three 0.6 mm diameter holes will be drilled in the first group of 15 blocks; 0.7 mm holes in the second group of 15 blocks; and 0.8 mm holes in the last group of 15 blocks. Lubricant will be used throughout the drilling procedure to prevent burning of the bone. The specimens will be maintained in a solution of 0.2% sodium azide to prevent bacterial growth.

Progress: Resident graduated, completed groups A & C but not B. He PCS'd to Ft Benning, GA.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 91-62		**Status** Ongoing
Title:	Parotid Gland Biopsy and Transbronchial Lung Biopsy in the Diagnosis of Sarcoidosis: A Comparison Study		
Start Date: Jul 91		**Est. Compl. Date:**	
Principal Investigator(s): MAJ R. Terry Ellis, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dentistry/Pulmonary		**Associate Investigators:** COL Michael W. Tabor, DE COL David M. Lewis, DE LTC Warren L. Whitlock, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To relate the involvement of the lungs and parotid gland in sarcoidosis.

Technical Approach: Patients with strong suspicion of sarcoidosis undergo open biopsy of parotid and transbronchial lung biopsy under intravenous sedation. OMS Staff or residents perform intravenous sedation and parotid gland biopsy, then transbronchial lung biopsy is performed by Pulmonary Staff physicians. Tissues are then evaluated by COL David Lewis, Staff Oral Pathologist.

Manpower: Existing clinic staff is utilized.

Number of subjects enrolled to date: 21

No adverse reactions.

Progress: Currently continuing to enroll subjects.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-31	**Status** Complete	
Title: A Clinical Study of the Relationship Between Computed Tomography and Bone Sounding			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Michael A. Billman, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** LTC Benjamin Hanson, DC COL William A. Brennan, DC COL Michael W. Tabor, DC LTC Thomas Ralston, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: The anatomic surface topology of planned implant sites as recorded by CAT Scan and the bone mapping technique will be compared for accuracy, time and cost.

Technical Approach: Through the use of a location guide stent the bone is measured using the bone map technique and the CAT Scan.

Number of subjects enrolled to date:

Progress: Still collecting CT Scan to compare with clinical data.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-56	**Status** Ongoing	
Title: A Clinical Evaluation of Autogenous Iliac Bone Grafts in Periodontal Osseous Defects			
Start Date: Jun 92		**Est. Compl. Date:** Jun 94	
Principal Investigator(s): COL Benjamin S. Hanson, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** COL William Brennan, DE	
Key Words: Periodontitis, Iliac graft			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To investigate the feasibility of the use of autogenous frozen marrow as a treatment modality in periodontal osseous defects.

Technical Approach: Twenty patients with hopeless teeth will be asked to participate in this study. Bone will be harvested from the ilium and stored in MEM at -6 C. Seven days after the cores have been taken they will be placed in periodontal defects.

Number of subjects enrolled to date: 11

Progress: Continuing to enroll patients.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-57	**Status** Completed	
Title: Evaluation of the Benefits of Screening Tests Done Prior to Periodontal Therapy			
Start Date: Jun 92		**Est. Compl. Date:** Jun 93	
Principal Investigator(s): COL Benjamin S. Hanson, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** COL William Brennan, DE	
Key Words: Screening tests			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the value of adjunctive screening lab tests before periodontal therapy.

Technical Approach: One hundred patients over the age of 40 will be selected at random and referred for biochemical and hematologic profiles. The tests will include CBC, UA, SMAC-17, PT, PTT, and platelet count.

Number of subjects enrolled to date: 100

Progress: Data collection is complete. Article has been written.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol#** 92-58	**Status**	Ongoing
Title:	A Comparison of the Clinical Success of the 5mm Nobelpharma Implant Fixture to the Standard 3.75mm Fixture		
Start Date:		**Est. Compl. Date:**	Jun 93
Principal Investigator(s): LTC Eric Adrian, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To study the clinical success of the 5mm fixture at 1, 2 and 3 year intervals.

Technical Approach: Clinical and radiological parameters will be used to compare the new fixture to the 3.75mm fixture.

Number of subjects enrolled to date: 15

Progress: Presently enrolling more subjects.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-74	**Status** Complete	
Title: Wear and Cutting Efficiency of the Rispi-sonic File			
Start Date: July 1992		**Est. Compl. Date:** April 1994	
Principal Investigator(s): MAJ Gordon W. Woollard, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:** COL P. Primack, DE Dr. R. Anderson Dr. F. Rueggeberg Dr. J. McPherson Mr. J. Horner	
Key Words: sonic; rispisonic; file; efficiency			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the cutting efficiency of Rispi-sonic files used in a MM 1500 endosonic system.

Technical Approach:

Progress: Protocol complete. Thesis defense, May 1994.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-75		**Status** Complete
Title:	The Effects of Intracanal Medicaments, Cements (sealers), and Fillers on Fibroblast Growth and Attachment to a Tooth Which Has Received Root Canal Therapy		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Lawrence G. Breault, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the effects that the placement of intracanal medicaments, fillers, and cements in endodontically treated teeth may have on periodontol regenerative procedures.

Technical Approach: Various medications were placed in roots and then cultured with fibroblasts. MTTs assay was done to determine all viability.

Progress: Complete for thesis defense, May 1994.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-76	**Status** Complete	
Title: Endogenous Prostaglandin Induced by IL-1B and TNFa Regulates IL-6 Production by Human Gingival Fibroblasts			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Charlene A. Czuszak, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To elucidate a mechanism by which the interaction of cytokines, such as I1-1B and TNFa, may promote IL-6 production.

Technical Approach: Fibroblast were grown with IL-1B or TNFa and the cultures were assayed for PG2 and IL-6. Cultures were done with and without indomethacin. Data collection is complete

Progress: Complete for thesis defense, May 1994.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-77		**Status** Ongoing
Title:	The Effect of Transforming Growth Factor Beta (TGF-B) in Conjunction with Polyols on Wound Healing Rats		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC George E. Tolson IV, DC		**Facility:** Animal Support Facility, Clinical Investigation	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To examine the effects of parenterally administered Transforming Growth Factor Beta in combination with topically applied pluronic polyols F-68 and F-127 on the tensile strength and healing of incisional wounds in the rat.

Technical Approach: Various concentration of F-68 and F-127 are applied to a standard wound in a rat. The tensile strength of the incision is then determined with the Instrom unit at the time of sacrifice.

Progress: Completed wound tensile strength studies; currently processing and staining tissue samples for PCNA, collagen, and factor 8.

Problems Encountered: (1) Delays in obtaining stain kits; and (2) it has been found that formalin fixed tissue over 2-3 days do not react well with the intranucleur stains. Antigen retrieval has provided limited success. Difficulties interacting with the histology section of the hospital concerning charging for histology services.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-2	**Status** Complete	
Title: Sealing Ability of Bases and Cements Following Exposure to 30% Hydrogen Peroxide and Sodium Perborate			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Jeffery D. Luzader, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** LTC Patrice D. Primack, DE LTC Robert J. Loushine, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective:

Technical Approach:

Progress:

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-3		**Status** Terminated
Title:	Stereomicroscopic Evaluation of Apical Retropreparation Shapes Utilizing an Ultra-sonic versus a Micro-head Handpiece		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Thomas F. Armstrong, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** LTC Patrice D. Primack, DE LTC Robert J. Loushine, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-11	**Status** Completed
Title:	The Effect of Bone Marrow Storage on Interleukin-6 Production Using the HLA: (FCR)BR		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Frederick C. Bisch, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** LTC Benjamin S. Hanson, DC COL William A. Brennan, DC LTC Michael A. Billman, MC LTC Val L. Kudryck, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: Determine the effects of storage temperature and time on IL-6 production.

Technical approach: Culture osteoblasts and then store for various time frames from 1 day to 14 days at temperatures ranging from 4° C to 70° C and assay for IL-6 production.

Progress: Complete.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-12		**Status** Ongoing
Title:	The Effects of Transforming Growth Factor Beta and Platelet Derived Growth Factor on Human Gingival Fibroblasts and Human Periodontal Fibroblasts Grown in Serum and Serum Free Media		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Thomas J. Butts, DE		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** COL William A. Brennan, DE LTC Benjamin S. Hanson, DE LTC Michael A. Billman, DE LTC Val L. Kudryk, DE MAJ Donald E. Sutherland, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: Determine if the use of TGF-B & PDGF might enhance second healing.

Technical Approach: Fibroblast are grown in vitro and then cultured with TGFB or PDGF.

Progress: Cells are then surveyed for viability and growth. Presently gathering data.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-39	**Status** Terminated
Title:	The Efficacy of Procera Laser Welded Hybrid Restorations		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Eric D. Adrian, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL John Agar, DC COL Michael Billman, DC COL Michael Gardner, DC COL James Hughbanks, DC LTC Ben Hanson, DC LTC Max Gaston, DC LTC Elise Adrian, DC LTC Stephen Cameron, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To compare the clinical performance of Procera laser welded hybrid restorations to the current lost wax cast framework technique in the restoration of human mandibular edentulous patients.

Technical Approach: The study includes a randomly assigned control group consisting of implant supported restorations made with a cast nobel alloy framework. All patients will be treated with a minimum of five Branemark system implants per patient and a hybrid cantilevered prostheses.

Number of subjects enrolled for the reporting period:

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-48	**Status** Terminated	
Title: An Average Mandibular Anterior Implant Angle			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Walter J. Morris, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael F. Gardner, DC COL Max Gaston, DC LTC Eric Adrian, DC LTC Eladio DeLeon, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To evaluate existing radiographs to see if a significant mandibular anterior implant trajectory angle or range of angles can be used to guide the placing of mandibular anterior implants.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-49	**Status** Terminated	
Title: A Comparison of Luting Cements for the CeraOne Abutment System			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ James E. Parker, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Max Gaston, DC LTC Eric Adrian, DC Michael F. Gardner, DDS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To evaluate the effectiveness of different luting cements on the retention of a ceramic crown and titanium implant abutment using the Instrom to measure retention forces.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 14 Oct 93 **Protocol** 94-4 **Status** Ongoing	
Title: The Mechanism of Nicotine Suppression of Fibroblast Integrin Expression in Vitro	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Harold B. Snyder, DE	**Facility:** Tingay Dental Clinic
Department/Service: Dental	**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE LTC Val Kudryk, DE MAJ David Craft, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 94, Continue

Objective: To determine the mechanism of B1 integrin subunit suppression by nicotine.

Technical Approach: Human gingival fibroblasts will be cultured in different concentrations of nicotine. These concentrations will simulate levels or concentrations of nicotine which one would expect to find in the tissues of smokers. Newly synthesized B1 integrin subunits will be isolated, identified and quantitated in an effort to determine at what point during biosynthesis nicotine has a deleterious effect on B1 integrin expression.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 14 Oct 93 **Protocol** 94-5 **Status** Complete	
Title: Binding Characteristics of Gallium to Dentin, in Vitro	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ William F. Bruce, DE	**Facility:** Tingay Dental Clinic
Department/Service: Dental	**Associate Investigators:** LTC Val Kudryk, DE COL Michael Billman, DE LTC Benjamin Hanson, DE
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Objective: To evaluate the binding characteristics and permeability of gallium on untreated dentin and dentin conditioned with either citric acid or tetracycline.

Technical Approach: The isotope work will be done at the Medical College of Georgia under their NRC license.

Number of subjects enrolled for the reporting period:

Progress: Most of data has been collected and have submitted research proposal to Medical College of Georgia.

Problems Encountered: Added section addressing binding to dentin in powdered form. Modified section binding to dentin wafers to compensate for evaporation of isotope.

DETAIL SUMMARY SHEET

Date:	14 Oct 93 **Protocol** 94-6		**Status** Ongoing
Title:	Evaluation of Pluronic Polyols on Regeneration in Rat Calvaria		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Edward Fowler, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE LTC Val Kudryk, DE James McPherson, III, PhD Henry Chuang, PhD MAJ Steven Tobias, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To determine the effects of pluronic poyols on bone regeneration.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Animal procedure completed; specimens harvested. Scheduled to present project at Medical College of Georgia in Nov 94.

Problems Encountered: New methods of data collection added, problems encountered included coordination with experts in soft x-ray and digitization at VA and MCG respectively has taken about 2 1/2 months.

DETAIL SUMMARY SHEET

Date:	14 Oct 93 **Protocol** 94-7		**Status** Terminated
Title:	Identification and Characterization of Murine Osteoclasts by Histochemistry, Electron Microscopy, and Immunophenotypic Markers		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Benjamin Hanson, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** MAJ David Craft, MS COL Michael Billman, DE LTC Val Kudryk, DE Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To develop methods for the unequivocal identification of osteoclasts so that research into osteoclast differentiation and function can be carried out.

Technical Approach:

Progress: None

Problems Encountered: We were unable to grow osteoclasts on a consistent basis.

DETAIL SUMMARY SHEET

Date:	14 Oct 93 **Protocol** 94-8	**Status** Ongoing	
Title:	The Effect of Dexamethasone on Human Gingival Fibroblast Proliferation, Collagen Production, and Integrin Expression and Distribution		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Val Kudryk, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE MAJ David Craft, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To determine effects of various concentrations of dexamethasone on HGF proliferation.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol** 94-9	**Status** Ongoing
Title:	A Comparison of Endodontic Files After Cleaning with Dual Enzymatic Ultrasonic Cleaner and Conventional Detergent Ultrasonic Cleaner and the Evaluation for the Presence of Viable Bioburden After Autoclave and Chemical Vapor Sterilization: A Scanning Electron Microscope Study		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Mary Johnson, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** MAJ David Craft, MS Jack Horner, DAC COL Patricia Primack, DE LTC Robert Loushine, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To evaluate and compare the two ultrasonic cleaning methods for endodontic files: use of conventional detergent cleaner and the use of a dual enzymatic ultrasonic cleaner and to determine if any viable bioburden remains on the instruments after steam and chemical vapor sterilization.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	14 Oct 93 **Protocol** 94-10		**Status** Ongoing
Title:	Sealing Ability of Bases and Cements Following Exposure to 30% Hydrogen Peroxide and Sodium Perborate		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Jeffery Luzader, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC Patricia Primack, DE LTC Robert Loushine, DE Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To identify a base or cement that will insulate standard root canal fillings from the degrading effects of 30% hydrogen peroxide and SP.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol** 94-11	**Status** Ongoing
Title:	Comparison of Nickel: Titanium Finger Spreaders to Conventional Spreaders for the Ability to Approach the Apex of Curved Canals.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Keith A. Berry, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Patrice D. Primack, DE LTC Robert J. Loushine, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To demonstrate the capability of the newer, flexible, Nickel: Titanium finger spreaders to adapt to curved root canal systems to within 1mm of the prepared root canal working length.

Technical Approach: Fifty mandibular molars will be selected by virtue of having mesial roots with a curvature of at least thirty degrees. The teeth will be stored in 10% neural buffered formalin. These teeth will be cleaned and shaped in the traditional manner with files (K-flex files; Kerry Sybron, Romulus, MI) and Gates Glidden burs (Union Broach Corp., Long Island City, NY) to accomodate obturation by lateral condensation. Irrigation will be provided by sterile saline with a standard step-back technique. The canals will be dried with paper points (Kerr Sybron; Romulus; MI). Endodontic spreaders described above will be inserted passively into the prepared canals until they meet resistance. Finger spreaders that approximate the size of the D11T spreader will be used. Measurements will be made from the same position as used during filing. Radiographs will be taken from mesial-distal and from a buccal-lingual direction to determine the position of the end of the spreaders in relation to the canal working length and the point at which the spreaders bind against the canal walls. The data obtained will be analyzed by Repeated-measures Analysis of variance.

Number of subjects enrolled for the reporting period:

Progress: Twenty experimental teeth cleaned and shaped; radiographic measurement of spreader lengths in canals made; will complete project after statistical analysis of results.

DETAIL SUMMARY SHEET

Date: 18 Nov 93	**Protocol** 94-12	**Status** Ongoing	
Title: Histological Response to Alloplast Implants in Extraction Sites in Pigs			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Glenn A. Greene, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC James Strider, DE LTC Benjamin Hanson, DE COL David Lewis, DE MAJ David Craft, MS Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To determine if this alloplastic ingredient acts as an osseoconductive material or as a non-irritating filler.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 14 Apr 94	**Protocol** 94-49	**Status** Ongoing	
Title: Women's Health Care Issues: The Incidence of Localized Osteitis in Female Soldiers Using Norplant Contraceptives			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Jim Strider, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Ricney Newhouse, DE MAJ Jim Duke, DE LTC Benjamin Hanson, DE LTC Dennis Runyan, DE James McPherson, III, PhD, DAC	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To compare and evaluate post-operative localized osteitis following molar extractions among patients who are currently being administered Levonorgstrel (NOR-PLANT) with the female population who are taking no systemic birth control.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 12 May 94	**Protocol** 94-57	**Status** Ongoing	
Title: Evaluating the Existence of Bennett Movement			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Michael Craddock, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Craddock, DE COL Max Gaston, DE COL Stephen Hanson, DE LTC Merle Parker, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:**	

Objective: To geometrically explain how Pantographic tracing artifacts mimicking Bennett's movement can be produced on pantographic tracing by rotational movement. Present a technique that can differentiate between pantographic tracing artifact and true Bennett's movement, thus providing the foundation for patient evaluation to confirm whether Bennett's movement actually exists or not.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 12 May 94	**Protocol** 94-58	**Status** Ongoing	
Title: Effects of Thread Removal of Endosteal Implants Upon Shear Loading			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert Rosenheimer, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental/Clinical Investigation		**Associate Investigators:** COL Max Gaston, DE COL Stephen Hanson, DE LTC Merle Parker, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:**	

Objective: To investigate the effect thread removal has upon the strength of a dental implant under shearing forces.

Technical Approach: Ten 15 millimeter Branemark titanium implants will be used in a pilot study to determine the statistically significant sample size (of implants) required for the study. Two groups of five implants will be established. Those in the first group of five will not be modified and serve as the control. The second group of five implants will have 5mm (measured from collar of the implant to its apical portion) of its threads removed, using a machining lathe with calibrated controls. Thread removal will be defined as complete when all remnants of the threads are deemed visually removed. Variations in the amount of thread removal will be recorded using a digital caliper. Values such as modules of elasticity, toughness, proportional limit, and ultimate shear strength will be compared for each of the two groups. All results will be statistically analyzed using a one way ANOVA.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Jun 94 **Protocol** 94-65	**Status** Ongoing	
Title:	Women's Health Care Issues: The Effects of Estrogen Levels on Osseointegration of Dental Implants		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Benjamin Hanson, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael A. Billman, DE LTC Larry Kudryk, DE COL Richney F. Newhouse, DE LTC Jim W. Strider, Jr., DE LTC Dennis A. Runyan, DE LTC Stephen M. Cameron, DE MAJ David W. Craft, MS	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:**	

Objective: To compare and evaluate the success of dental implants in a female soldier population. The aim of the study is to determine if an associations exists between sex hormone levels and the osseointegration of dental implants.

Technical Approach: The patient population will be divided into three groups. The first group will consist of patients who are presently using systemic birth control. The second patient population will consist of individuals not employing systemic birth control. The third group will consist of male soldiers who will be enrolled in the study as a negative control.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	10 Mar 94 **Protocol** 94-68		**Status** Ongoing
Title:	Wear and Cutting Efficiency of the Nickel Titanium Rotary Files		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Michael Ford, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** Frederick Rueggeberg, MCG COL Patrice Primack, DE Ronald Anderson, MCG Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objective: To determine the cutting efficiency of NT rotary files.

Technical Approach: All of the NT files will be viewed before initial use at 600X under the scanning electron microscope. The files and their corresponding flutes will be measured new, midrange and last use.

Number of subjects enrolled for the reporting period:

Progress: Model progressing well; well accepted by major advisor and research committee.

Problems Encountered: Change in test from bovine bone to a more homogenous ceramic.

DETAIL SUMMARY SHEET

Date: 08 Sep 94 **Protocol** 94-74 **Status** Ongoing	
Title: The Proteolytic Activity of Porphyromonas gingivalis and Prevotella intermedia Against Heme-binding Plasma Proteins	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ David R. Reeves, DE	**Facility:** Tingay Dental Clinic
Department/Service: Dental	**Associate Investigators:** Geoffrey R. Tompkins, PhD, MCG COL Michael Billman, DE COL Benjamin S. Hanson, DE MAJ David W. Craft, MS
Key Words:	
Accumulative MEDCASE cost:	**Periodic Review Results:**

Objective: To determine if P. gingivalis and P. intermedia possess an enzyme (proteolytic) that assists in the acquisition of heme even in the presence of heme-binding proteins that would seem to resist the acquisition of heme by the pathogens and if an enzyme (proteolytic) specific for heme-binding proteins exists, which protease inhibitors can be selectively added to the assay in order to decrease or eliminate the viability of the enzyme.

Technical Approach: The enzymatic activity of these bacteria will be tested (in vitro) against dialyzed whole human plasma. During incubation of the bacteria with plasma, samples will be separated and analyzed. The investigator has chosen to study hemopoxin and haptoglobin to test the possibility of P. gingivalis and P. intermedia break apart these hemopexin-heme and haptoglobin-hemoglobin complexes. Once these complexes are separated the bacteria may uptake and use the free heme. The investigator will analyze the enzymatic activity of these bacteria in order to assess this possibility and analysis will be made as to the potential chemical inhibitors of these enzymes.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 08 Sep 94 **Protocol** 94-75 **Status** Ongoing	
Title: The Effects of Titanium Abutments of Cement Removal	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): COL John A. Agar, DE	**Facility:** Tingay Dental Clinic
Department/Service: Dental	**Associate Investigators:** LTC Stephen M. Cameron, DE COL James C. Hughbanks, DE COL Dennis A. Runyan, DE COL Max L. Gaston, DE
Key Words:	
Accumulative MEDCASE cost:	**Periodic Review Results:**

Objective: To investigate and compare the surfaces of abutments following the removal of three different cements (glass ionomer, resin, and zinc phosphate) using three different instruments (gold plated scaler, rigid plastic scaler, and stainless steel explorer).

Technical Approach: Five board certified prosthodonitsts will remove each cement using each instrument for a total of nine samples for each investigator. The investigators will determine the method for removing cements from titanium abutments that cause the least damage to the original, smooth, machined surface.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 08 Sep 94	**Protocol** 94-76	**Status** Ongoing	
Title: A Comparison of Two Impression Techniques for Accuracy of Occlusal Contacts			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): COL Merle H. Parker, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC Stephen M. Cameron, DE COL James C. Hughbanks, DE COL Max L. Gaston, DE LTC David Reid, DE	
Key Words:			
Accumulative MEDCASE costs:		**Periodic Review Results:**	

Objective: To investigate and compare the accuracy of interocclusal relationships of articulated casts from a closed mouth impression technique and a full arch conventional impression technique.

Technical Approach: Interocclusal records made with Blue-Mousse will be used for the evaluation. Each point of occlusal contact on the intraoral record will be visually identified and selected if it's thin enough to transmit light. An interocclusal record will be made from the articulated casts of each of the two impression techniques. For each of these points, the other two registrations will be evaluated to see if there is a corresponding point or not.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 08 Sep 94 **Protocol** 94-78 **Status** Ongoing	
Title: The Effects of Tetracyclines on Murine Bone Cell Cultures (Mus Musculus)	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Gary D. Swiec, DE	**Facility:** Tingay Dental Clinic
Department/Service: Dental	**Associate Investigators:** MAJ David W. Craft, MS COL Michael A. Billman, DE COL Benjamin S. Hanson, DE LTC Val L. Kudryk, DE CPT Kim D. Vlach, MS, DVM SPC Demetrius Collins, Vet Technician
Key Words:	
Accumulative MEDCASE cost:	**Periodic Review Results:**

Objective: To determine the effect of varying doses of tetracycline on mouse bone cells grown in a dish.

Technical Approach: The mice will provide an immature supply of bone cells which mimics the situation found around diseased human teeth during surgery, just prior to placement of the tetracycline/graft mixture. The investigator will harvest and grow bone cells from mice in 12-well plastic tissue cultures plates. Cell cultures grown both with and without tetracycline will be followed for 20 days. Cell cultures will be observed microscopically for growth. Specific activity of bone producing cells, or osteoblasts, will be analyzed by staining for alkaline phosphates activity. Growth media cell cultures will be sampled, stored at 70 degrees C and assayed for cytokine and osteocalcin presence. The results of this study will aid in the treatment of soldiers with periodontal disease.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 08 Sep 94 **Protocol** 94-77 **Status** Ongoing	
Title: Emergency Medicine Trauma Lab (Sus Scrofa)	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Robert Suter, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Emergency Medicine	**Associate Investigators:** MAJ Jerry Fenwick, MC MAJ Sarah Mack, MC Joyce Norman, MD Ivy Shuman, MD Brendan O'Hara, MD F.P. Craig Miner, MD CPT Jeffrey Brasfield, MS, PA CPT Daniel Cruser, MC
Key Words:	
Accumulative MEDCASE cost:	**Periodic Review Results:** Oct 94, Continue

Objective: The objective of this protocol will be basic proficiency training of physicians (interns and residents) working in the Emergency Department with necessary life-saving procedures and as a refresher proficiency training of staff health care providers. This lab will also reinforce skills learned in the ATLS course.

Technical Approach: Each session will consist of up to four interns/residents and will utilize one pig. Several standard procedures will be performed on the pig allowing maximal use of each pig when training physicians. The estimated number of procedures to be taught is up to 48 students per year during 12 sessions per year.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-14	**Status** Terminated
Title:	Smoking Cessation in Active Duty Army Trainees: The Effects of Direct Health Care Provider Advice and Follow-up		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): CPT John Littell, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** CPT Charles Stargel, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: Trainees will be identified and surveyed at the time of both in and outprocessing (variable time frame usually 2-4 months) to determine the effectiveness of direct Health Care Provider (HCP) advice/counselling. The intervention and followup visits are to be arranged in conjunction with the trainee's command and excused by sick slip to insure compliance. Study design: Prospective quasi-experimental study, to ascertain behavior modification secondary to direct HCP advice alone and subsequently more extensive HCP counselling in a second group, as compared to a similar group without either of these interventions (total groups - 3). Investigator believed that composition of trainees is comparable among the three TMC's.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Principal investigator ETS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-25	**Status** Ongoing	
Title: HELLP Syndrome: The Incidence - A Prospective Study			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): CPT Kenneth Trzepkowski, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice/OB-GYN		**Associate Investigators:** LTC Wayne Blount, MC LTC Kevin Kelly, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To determine the incidence of HELLP and determining clinical characteristics associated with the development of the syndrome.

Technical Approach: Measure serum marers prospectively on volunteer pregnant patients.

Number of subjects enrolled to date: 199

Progress: Date collection near completion. Approximately 150 patients have been entered into SPSS.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-32	**Status** Terminated
Title:	Infant Feeding Practices in the Military Community: The Incidence and Duration of Breast Feeding in the Military Community and the Factors Affecting this Decision		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ B. Wayne Blount, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Cindy Lee, MC John Kugler, MD Dana Anderson, MD Evelyn L. Lewis, MD Kathy Holder, MD William Blanke, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objectives: To determine the incidence and duration of infant feeding methods of women in the military community. To determine the incidence and duration of breast feeding in active duty women as a subset of employed mothers. To identify the factors affecting women's infant feeding decisions, specifically those affecting active duty women.

Technical Approach: Questionnaire will be completed by post-partum patients. Telephone or mail contact of subjects at six months for followup data.

Number of subjects enrolled to date: 25 active duty and 50 dependent women.

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-62	**Status** Terminated	
Title: A Survey of Resident Perceptions of Effective Teaching Behaviors in Different Residencies			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): CPT J. Gregory Jolissaint, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** CPT David P. Goldman, MC LTC B. Wayne Blount, MC LTC Robert Webb, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objectives: This study is designed to inform faculty members of different residency programs of teaching behaviors their house officers deemed most helpful to their learning process in residency (as well as those felt to be least helpful). By "arming" faculty members with this information during faculty orientation and/or faculty development sessions, there should be a resultant improvement in training for physicians at DDEAMC and ultimately higher quality patient care delivered by graduates of DDEAMC residencies.

Technical Approach:

Number of subjects enrolled to date:

Progress: Principal investigator PCS'd. Protocol terminated.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol** 94-25	**Status** Terminated
Title:	A Longitudinal Study of Breast Cancer Screening in a Military Beneficiary Population Stratified by Risk		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ B. Wayne Blount, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** COL Kent Plowman, MC CPT Cynthia Benfanti, MC Laura Davidson, PhD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objectives: To determine the reasons why women do not participate in recommended screening for breast cancer.

Technical Approach: The first phase will involve answering a questionnaire which asks for demographic information plus data which will allow a risk factor to be calculated. All women who have an increased risk of breast cancer from this calculation plus an equal number of women at lower risk of breast cancer will be asked to participate in another study to examine compliance in breast cancer screening. This study will also involve taking several standard psychological tests several times.

Number of subjects enrolled to date:

Progress: Principal investigator has left the service. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 10 Feb 94	**Protocol** 94-39	**Status** Terminated	
Title: Lead Screening in the Army and the Use of High Risk Profiles			
Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC B. Wayne Blount, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** LTC Joseph White, MS CPT Michael Huffnagle, MC CPT Michael Johnson, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objectives: To assess the usefulness of the modified CDC questionnaire in identifying children at risk for lead toxicity, save the Army thousands of dollars by possibly stopping universal lead screening, identifying the high risk factors of Army children for lead poisoning, and identifying low risk and high risk Army communities for community-specific lead screening programs.

Technical Approach:

Number of subjects enrolled to date:

Progress: Principal investigator has left the service. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 10 Feb 94	**Protocol** 94-40	**Status** Ongoing	
Title: Assessment of the Provision of Clinical Preventive Services and Immunizations			
Date:		**Est. Compl. Date:**	
Principal Investigator(s): COL Lynda A. Linker, COL, AN		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** COL Angela Dingbaum, AN Carol Gorman, RN, MCG LTC Wayne Blount, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Objectives: Review records to assess the current status of preventive services and immunizations received by patients at DDEAMC and to propose recommendations for methods, tolls, and/or programs to meet the objectives if the assessment indicates less than 50% of the patients have received the recommended services.

Technical Approach: (1) Assess the proportion of patients who have received the minimum clinical preventive services by reviewing a random sampling of outpatient medical records; (2) if results of assessments indicate less than 50% of the records document the minimum recommendations, develop proposals for methods, tool, and/or programs to assist health care providers with ensuring recommended clinical preventive services and immunizations are provided to their patients; and (3) if results of assessment indicate less than 50% of the records document the minimum recommendations, develop proposals for methods, tools, and/or programs to assist patients in assuming greater responsibility for their own health.

Number of subjects enrolled to date:

Progress:

DETAIL SUMMARY SHEET

Date: 14 Apr 94 **Protocol** 94-47 **Status** Terminated			
Title: The Incidence, Etiology, and Consequences of Depression in Women During Their Childbearing Years and Its Effects on Perinatal Development			
Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC B. Wayne Blount, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Laura Davidson MAJ Elaine Correnti, MC Andree Lloyd, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objectives: To evaluate social, psychological, and biological components of depression in women between the ages of 18 and 45.

Technical Approach: The project will compare depression that occurs following childbirth (postpartum depression; PPD) to depression that occurs during other times for women in this age range. The efficacy of various treatment strategies for nonpregnant, pregnant, and postpartum women will also be evaluated. All women will be assessed for depression at three month intervals for a minimum of three years. Data will be collected about family and social functioning, life events, symptom experiences, and biochemical profiles. All women who become pregnant during the study period will be followed for a minimum of one year following parturition. The impact of maternal depression will also be examined in the neonate. Infants born to all mothers during the study period will be evaluated at one year. Mother-infant interactions and offspring behavior will be compared between depressed and non-depressed mothers.

Number of subjects enrolled to date:

Progress Principal investigator left the service. Protocol terminated.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 90-16		**Status** Terminated
Title:	Study of Vespa Fire Ant Venom in the Diagnosis of Fire Ant Reactivity		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Angelina J. LePage, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Allergy		**Associate Investigators:** Chester Stafford, MD, MCG Richard T. Hatch, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare skin test reactivity of Vespa fire ant venom to that of two commercially available IFA whole body extract preparations.

Number of subjects enrolled to date: 35 adults
Number enrolled for reporting period:

Progress: The study in adults has been completed and results published. There were 35 adults enrolled. According to Dr. stafford, the study hopes to include children but at this time there are none enrolled and no progress to report.

DETAIL SUMMARY SHEET

Date:	27 Oct 93 **Protocol** 91-14		**Status** Ongoing
Title:	Comparison of Intravenous H-2 Antagonists and Their Influence on Gastric Emptying on Insulin Dependent Diabetics		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): CPT Michael P. Goldfinger, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** CPT Eugene H. Ryan, MC Staff Internist, Fort Rucker, Alabama LTC Stephen G. Oswald, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93, Oct 94, Continue	

Study Objective: To study the effect of a single standard IV dose of famotidine, cimetidine and ranitidine on GE in adult diabetics.

Technical Approach: Each patient will be studied in the fasting state on four different days spaced at least 72 hours apart. Prior to each gastric emptying study the subjects will receive an IV bolus injection of either one of cimetidine, ranitidine, famotidine, or placebo.

Number of subjects enrolled for the reporting period: 11 (2 female)

Problems Encountered: Limited ability to perform gastric emptying study in Nuclear Medicine. One study a week limited us to one patient per month (4 studies per patient).

Progress: Eleven patients completed study. Preliminary analysis of data is presently being performed.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-9		**Status** Ongoing
Title:	A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 400 mg (I x 400 mg capsule) in the Fed and Fasted State and Augmentin Amoxicillin/Clavulanate 1.5 gm (I x 500 mg tablet TIC) in the Fed State in the Treatment of Acute Exacerbations of Chronic Bronchitis		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne T. Honeycutt, MC MAJ Jesse J. Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To compare the efficacy, safety, and primarily, the GI tolerance of once-daily Cedax ceftibuten (SCH 39720) in both the fed and fasted state with that of Augmentin amoxicillin/clavulanate given TID int he fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 6

Progress: Over 70 patients have been screened and 24 patients have been enrolled. The protocol will end in 1993. There have been positive results in most patients without complications. We hope to finish enrollment before the end of the protocol.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-10		**Status** Ongoing
Title:	A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 300 mg Given BID and Augmentin 500 mg Given TID in the Treatment of Community Acquired Pneumonia		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne T. Honeycutt, MC MAJ Jesse J. Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To compare the efficacy, safety, and tolerance of high-dose ceftibuten (SCH 39720) 300 mg BID with that of augmentin 500 mg TID in the treatment of pneumonia in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 5

Progress: Over 30 patients have been screened with 12 patients enrolled. The protocol will continue in 1994. Major problems have been isolation of the causative organism on cultures. The laboratory has started doing double culture plates to increase the diagnostic yield.

DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 92-30	**Status** Ongoing
Title: Techniques of Use of Metered Dose Inhalers	
Start Date: Apr 92	**Est. Compl. Date:** June 93
Principal Investigator(s): CPT Richard B. Hilburn, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Pulmonary Disease	**Associate Investigators:** MAJ Warren L. Whitlock, MC MAJ Jesse T. Doers, MC Ray Scarlett, CRT
Key Words: MDI, Metered dose inhalers	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 94, Continue

Study Objective: To evaluate the techniques of use of MDI by the EAMC patient population. To determine which of three teaching modalities is the most effective in improving technique. To detect any implication of impact of improved technique upon emergency room visits and hospitalizations for the study population.

Subjects enrolled to date: 106

Problems Encountered: Forty percent patient drop-out due to enrollment of patients living outside EAMC catchment area.

Progress: A manuscript has been written. The statistical analysis is being rerun. The enrollment of patients is complete. Pending final statistical results.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-47		**Status** Ongoing
Title:	A Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of *Mycobacterium Avium Complex* Disease in HIV Infected People		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): COL Daniel B. Craig, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Infectious Disease		**Associate Investigators:** MAJ Craig E. Smith, MC COL David R. Haburchak, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 count<100/ul.

Technical Approach: Treatment will follow outline per Pfizer protocol.

Subjects enrolled to date: 9

Progress: Nine patients screened. One patient did not meet entry qualifications, one patient dropped from study before receiving drug, one patient died while on study not related to drugs. Six patients continue on study.

DETAIL SUMMARY SHEET

Date:	27 Oct 93	**Protocol** 92-60	**Status** Terminated
Title:	A Double-Blind Randomized Parallel Study of the Antiemetic Effectiveness of IV Dolasetron Mesylate VS IV Zofran in Patients Receiving Cisplatin Chemotherapy (MCPR0031)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Karen J. Bowen, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Don W. Shaffer, MC MAJ Robert Krywicki, MC LTC Stephen G. Oswald, MC COL Charles T. Thornsvard, MC Lyle M. Glascock, PharmD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the relative effectiveness of a single 2.4 mg/kg intravenous (IV) dose of dolasetron mesylate versus a single 32 mg dose of IV Zofran for complete prevention of emesis due to ($\geq$ 70 mg/m^2) of cisplatin chemotherapy. To evaluate the safety and tolerance of dolasetron myesylate versus ondansetron when given for this indication. To compare patient satisfaction with the two antiemetic agents.

Technical Approach: This is a double-blind, randomized, parallel study in which patients with a history of histologically confirmed malignant disease will receive either IV dolasetron mesylate (2.4 mg/kg) or IV ondansetron (32 mg/kg). The cisplatin dose will be $\geq$ 70 mg/m^2 and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 17

Progress: The study objective and technical approach was amended in Nov 92 to include a single dose of Zofran as the comparative drug. There have been 12 patients enrolled and completed the study. There has been one serious adverse event - a Type I hypersensitivity reaction manifested by severe bronchospasm. The patient was treated with IV Benadryl, 50 mg, after Albuterol nebulizer therapy. The reaction subsequently subsided.

DETAIL SUMMARY SHEET

Date:	27 Oct 93 **Protocol** 92-61	**Status**	Terminated
Title:	A Five Arm Double-Blind Randomized Dose-Response Study of the Antiemetic Effectiveness of IV Dolasetron Mesylate in Patients Receiving Cisplatin Chemotherapy (MCPR0032)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Karen J. Bowen, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** LTC Stephen G. Oswald, MC MAJ Don Shaffer, MC MAJ Robert Krywicki, MC COL Charles T. Thornsvard, MC Lyle M. Glascock, PharmD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To establish efficacy by showing that there is a trend toward decreased emesis following cisplatin ($\geq$ 70 mg/m^2) with increasing doses of dolasetron mysylate. To evaluate the dose-response relationship across 0.6,1.2,1.8, 2.4, and 3.0 mg/kg single intravenous (IV) doses of dolasetron mysylate in preventing emesis due to cisplatin ($\geq$ 70 mg/m^2) chemotherapy. To evaluate the safety and tolerance of dolasetron mesylate when given for this indication. To characterize the population pharmacokinetic and pharmacodynamic models of dolasetron mysylate and/or its metabolite(s) and their interindividual variabilities in patients receiving cisplatin. To compare the degree of patient satisfaction among the antiemetic dose levels.

Technical Approach: This is a five arm, double-blind, randomized, dose response in which patients with a history of histologically confirmed malignant disease will receive a single dose of dolasetron mesylate. Patients of either sex and any race will be admitted to this study. They must be undergoing their first course of cisplatin-containing chemotherapy. The cisplatin dose will be $\geq$ 70 mg/m^2 and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 0

Progress: This study was not begun due to sponsor's request.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-78	**Status** Complete	
Title: A Multicenter, Open Label, Pilot Study of Azithromycin in the Outpatient Treatment of Lower Respiratory Tract Infection Due to Atypical Respiratory Pathogens			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate azithromycin in the treatment of lower respiratory tract infections due to the atypical respiratory pathogens *C. pneumoniae, M. pneumoniae and L. pneumophila.*

Technical Approach:

Number of subjects enrolled to date: Pneumonia (15); Bronchitis (33)

Progress: Sponsor asked to discontinue enrollment June 3, 1994. A total of 48 patients were enrolled: 33 patients had bronchitis, 15 had pneumonia.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-6	**Status** Terminated
Title:	Phase I, Trial of VP-16 + Immunex r-GM-CSF in Patients with Advanced Malignancies		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Don W. Shaffer, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Geoffrey R. Weiss, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Continue	

Study Objective: To estimate the maximally tolerated dosage, and frequency and types of toxicities of etoposide when combined with r-GM-CSF in patients with advanced malignancy; to determine which schedule of administration of r-GM-CSF (prior to or during etoposide delivered; to determine a superior in terms of the greater amount of etoposide delivered; to determine a recommended dosage and schedule for etoposide +/- r-GM-CSF to be used in Phase II trials; to document any responses which may be observed during treatment with the combined regimen; and to evaluate the effects of rHuGM-CSF on the flood levels of etoposide administered orally.

Technical Approach:

Number of subjects enrolled for reporting period: 2

Problems Encountered: Two patients who were enrolled in 1993 have since come off study due to progressive disease.

Progress: Study closed. Protocol terminated.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-26	**Status** Terminated	
Title: A Comparative Trial of 256U87 and Acyclovir for the Treatment of First-Episode Genital Herpes Infection			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Mark G. Blaskis, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:** MAJ Jerome C. Hill, MC MAJ William L. Heimer, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the efficacy of a new antiviral agent administered twice a day instead of five times a day as acyclovir is administered.

Technical Approach: Therapy will follow schema outlined in Burroughs-Wellcome protocol.

Number of subjects enrolled to date: 3

Progress: There have been three patients enrolled. One patient dropped out of the study after the first day because he didn't want to participate.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-30		**Status** Ongoing
Title:	A Multicenter Investigator Blinded Study of the Efficacy and Safety of Azithromycin vs Amoxicillin/Clavulanate in the Treatment of Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease (Chronic Bronchitis)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Jesse T. Doers, MC MAJ Wayne T. Honeycutt, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To compare the safety and efficacy of orally administered azithromycin and amoxicillin/clavulanate in the treatment of acute exacerbations of COPD (Chronic Bronchitis) Caused by susceptible bacterial pathogens.

Technical Approach: Therapy will follow schema outlined in Pfizer protocol.

Number of subjects enrolled to date: 7 (chronic bronchitis)

Progress: Seven patients enrolled on this protocol without major difficulties. All adverse events were not related to the drug and all patients ameliorated while under follow-ups in clinic. This study was closed by PREMIER 18 March 1994.

Problems Encountered: One patient had resistant pathogen, non-drug related.

Adverse Reactions: Adverse reactions included epigastric tenderness, rigid abdomen, rectal bleeding, throat erythema, UTI, kidney stone, GI bleed, and hypoxemia.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-31		**Status** Complete
Title:	A Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Three Doses of CP-0127 and Placebo in Patients with Presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary, Infectious Disease		**Associate Investigators:** MAJ Wayne T. Honeycutt, MC MAj Jesse T. Doers, MC MAJ Craig Smith, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the efficacy and safety of a 72-hour infusion of three doses of CP-0127 or placebo in the treatment of patients with SIRS and presumed sepsis.

Technical Approach: Therapy will follow schema outlined in Cortech protocol.

Number of subjects enrolled to date: 6 (septic patients)

Progress: Enrollment for this protocol was completed 06 April 1994 at sponsor's request. A total of six patients were enrolled of which two died. The deaths were not believed to be drug related.

Adverse reactions encountered: Death, rectal abscess, liver failure, thrombocytopenia, hyperglycemia, cardiac arrest, bradycardia, oxygen desaturations, and profound hypotension. None of the adverse reactions are believed to be related to the drug.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-51		**Status** Ongoing
Title:	A Study to Investigate the Efficacy and Safety of Oral Valacyclovir (1000 mg or 500 mg, twice daily) Compared with Placebo in the Treatment of Recurrent Genital Herpes in Immunocompetent Patients		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): COL Marshall A. Guill, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:** LTC Roger V. Bruce, MC MAJ Mark G. Blaskis, MC Susan Montieth, MT (ASCP)	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: This is a company sponsored study to evaluate the efficacy and safety of valacyclovir to placebo in treating recurrent genital herpes in immunocompetent patients. By using the parent compound to acyclovir with less frequent dosing and giving to patients at home so as to start treatment within hours of symptom occurrence, it is hoped that greater efficacy may be found than has been true of earlier studies with acyclovir. It has three arms consisting of the two dose levels and placebo.

Technical Approach: Approve as a company sponsored more than minimal risk human use study and forward to HSC for further disposition and for permission to accept the drugs and placebos from Burroughs-Wellcome.

Number of subjects enrolled to date: None

Progress: No patients yet enrolled

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-64	**Status** Complete
Title:	A Randomized, Double-Blind, Multicenter Trial Comparing 10 Days of Oral Therapy with CP-99,219 (100 mg or 300 mg Daily) or Ofloxacin (800 mg Daily) for the Treatment of Acute Exacerbation of Chronic Bronchitis		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne T. Honeycutt, MC MAJ Jesse T. Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To Investigate the efficacy and safety of two doses of CP-99,219 and Ofloxacin in the treatment of patients with acute exacerbations of chronic bronchitis.

Technical Approach:

Number of subjects enrolled to date: 4 (bronchitis)

Progress: Sponsor requested enrollment be stopped on 05 June 1994. A total of four patients were enrolled. Three patients dropped from protocol due to adverse events.

Adverse Events: Nausea, vomiting, queasiness, insomnia

DETAIL SUMMARY SHEET

Date: 14 Oct 93 **Protocol** 94-1 **Status** Ongoing	
Title: GITS versus Core-Coated Nifedipine: Comparison of Efficacy Viq 24 hour Ambulatory Blood Pressure Monitoring	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Michael A. Riel, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine	**Associate Investigators:** Fink, LM Goldfinger, MP Cooper, EB Tam, CD Bookstaver, DA
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 94, Continue

Study Objective: To determine the bioequivalence of Procardia-XL and Adalat-CC.

Technical Approach: Via a computerized search, 45 patients will be identified whose sole antihypertensive medication is Procardia-XL equally distributed among three dosing levels (30mg, 60mg, 90mg). This group of patients will have ambulatory blood pressure recordings obtained and then switched to the same dose of nifedipine in the Adalat-CC formulation. Three weeks following the switch, a second set of ambulatory blood pressure recording of the study patients will be obtained.

Progress:

Adverse reactions encountered:

DETAIL SUMMARY SHEET

Date: 14 Oct 93	**Protocol** 94-2	**Status** Ongoing	
Title: A Phase I/II Study of SDZ PSC 833 with Doxorubicin, Vincristine, Cyclophosphamide, and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Don W. Shaffer, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** COL Charles Thornsvard, MD MAJ Karen Bowen, MD LTC Stephen Oswald, MD COL Jayanti Sen, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To evaluate the efficacy (i.e., complete response rate and duration, disease free and overall survival) of P-DVCP in refractory or relapsed intermediate or high grade non-Hodgkin's lymphoma.

Technical Approach: In Phase I of this study, patients will be assigned chronologically to five cohorts as defined by escalating doses of doxorubicin and vincristine. A minimum of four and a maximum of six patients will be accrued to each cohort. Once the cohort is assigned, the same regimen will be administered every 21 days for a maximum of 6 cycles.

Progress:

DETAIL SUMMARY SHEET

Date: 18 Nov 93	**Protocol** 94-13	**Status** Ongoing	
Title: The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Coronary Heart Disease and Left Ventricular Dysfunction			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Michael D. Lecce, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Cardiology		**Associate Investigators:** LTC Farley Neasman, MC MAJ Matthew Smolin, MC MAJ James Wilkins, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To determine if oral d-Sotalol reduces total mortality in patients who had a myocardial infarction and have left ventricular dysfunction and to compare the safety and tolerance of d-Sotalol with placebo when administered long-term to patients with LV dysfunction.

Technical Approach: Eligible patients in the double-blind phase will be randomized to d-sotalol or placebo. Patients will receive oral d-sotalol 100mg or placebo BID for the first seven days. If tolerated, the dose will be increased to d-sotalol 200 mg or placebo BID for the remainder of the study. The study will be completed after all patients are enrolled and have been in the study for a minimum of 18 months. All randomized patients who discontinue study medication for any reason other than death will also be followed for the entire duration of the study.

Progress: The study was initiated in March and the first patient was randomized in July 94. There have been no adverse reactions encountered.

Number of subjects enrolled: 2 (one male with recent MI; one male with remote MI)

Problems Encountered: The inclusion criteria is difficult to meet.

DETAIL SUMMARY SHEET

Date: 13 Jan 94	**Protocol** 94-35	**Status** Ongoing	
Title: Elimination of Extrachromosomal DNA from Ovarian Cancer Patient's Tumor with Hydroxyurea Treatment			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): MAJ Don W. Shaffer, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** COL Charles Thornsvard, MC MAJ Robert Krywicki, MC CPT Karen Bowen, MC LTC Stephen Oswald, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To re-explore the use of hydroxyurea in patients with refractory advanced ovarian cancer.

Technical Approach: Enroll patients with advanced, refractory ovarian cancer with malignant ascites who are requiring weekly paracenteses for comfort. Will remove the ascites and examine the fluid for number of tumor cells, the amount of extrachromosomal DNA in the tumor cells (as assessed by cytogenetics) (double minute DNA) or by molecular biology techniques.

Progress: No patients have been accrued.

DETAIL SUMMARY SHEET

Date: 10 Feb 94	**Protocol** 94-41	**Status** Ongoing	
Title: Effectiveness of High Dose, Inhaled Triamcinolone Acetonide in Patients with Obstructive Airway Disease			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): CPT Carol R. Young, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** LTC Warren Whitlock, MC David Bookstaver, DAC Jorge Thompson, P.A. (FACT)	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To assess the effectiveness of high dose, inhaled triamcinolone acetonide (Azmacort) in bronchodilator responsive obstructive lung disease in patients on inhaled bronchodilators who are on low-dose (two puffs four time per day) inhaled corticosteroids.

Technical Approach:

Progress:

DETAIL SUMMARY SHEET

Date: 09 Jun 94	**Protocol** 94-62	**Status** Ongoing	
Title: A Randomized, Placebo-Controlled Trial of E5 Antiendotoxin Monoclonal Antibody in Patients with Severe Sepsis			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To investigate the efficacy of E5 in the reduction of mortality in patients with severe sepsis due to documented/probable gram-negative infection.

Technical Approach: Patients that qualify for the study will be randomized to receive either E5 antiendotoxin monoclonal antibody or matching placebo at a 1:1 ratio according to a computer-generated randomization code provided by the sponsor.

Progress:

DETAIL SUMMARY SHEET

Date: 09 Jun 94	**Protocol** 94-63	**Status** Ongoing	
Title: A Double-Blind, Parallel Group Evaluation of Salmeterol versus Placebo in the Treatment of Nocturnal Asthma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To characterize the efficacy of salmeterol, 42mg BID, when administered for 12 weeks to subjects with nocturnal asthmas; to characterize the safety profiles of salmeterol, 42mg BID, versus placebo BID, when administered over a 12 week period; and to evaluate the impact of salmeterol, 42mg, on quality of life dimensions (including sleeping) as compared to placebo BID in subjects with nocturnal asthma.

Technical Approach: Efficacy determinations will include symptom assessments, as well as daily peak flow measurements, and pulmonary function tests which will be performed Day 1 and after 4, 8, and 12 weeks of treatment. Subjects will be randomized into one of two strata: (1) subjects using theophylline, and (2) subject not using theophylline. Each subject will be evaluated during a two week basline period followed by a 12 week treatment.

Progress:

DETAIL SUMMARY SHEET

Date: 11 Aug 94	**Protocol** 94-67	**Status** Ongoing	
Title: A Multicenter Open-Label Study to Evaluate the Safety and Efficacy of Levofloxacin in the Treatment of Bacterial Infections			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC CPT Michael Nelson, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the safety of intravenous levofloxacin in the treatment of bacterial infections of the respiratory tract, skin, and urinary tract due to susceptible organisms.

Technical Approach: Study population will consist of male or female subjects, 18 years of age or older, with clinical signs and symptoms of bacterial infections of the respiratory tract, skin, or urinary tract requiring intravenous antibiotic therapy.

Progress:

DETAIL SUMMARY SHEET

Date:	11 Aug 94 **Protocol** 94-70		**Status** Ongoing
Title:	A Multinational Multicenter, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Aerosolized Recombinant Pulmonary Disease Experiencing a Pulmonary Exacerbation.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LTC Warren L. Whitlock, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue	

Study Objective: To compare 90-day all-cause mortality; to compare the number of re-hospitalizations, the change in quality of life and the safety of 14 day Pulmozyme or placebo treatment at 90 days; and to compare all-cause mortality at 180 days.

Technical Approach:

Progress:

DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 93-15 **Status** Terminated	
Title: Satisfaction with Patient Controlled Analgesia	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Mary Hardy, AN	**Facility:** Eisenhower Army Medical Center
Department/Service: Nursing	**Associate Investigators:** CPT Barbara Miller, AN CPT Michael E. Streeter, AN
Key Words: Analgesia patient controlled analgesia	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Study Objective: To determine patient satisfaction with postoperative pain control using the patient controlled analgesia (PCA) infuser, to identify the frequency of PCA use, and to identify problems associated with PCA use.

Technical Approach:

Number of subjects enrolled for reporting period: 40

Progress: Protocol terminated 31 December 1993.

DETAIL SUMMARY SHEET

Date:	12 May 94	**Protocol**	94-55	**Status**	Ongoing
Title:	Perceptions of Women on Active Duty about Their Health Problems/Needs				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Mary Hardy, AN			**Facility:** Eisenhower Army Medical Center		
Department/Service: Nursing			**Associate Investigators:** COL Joan Jack, AN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective:

Technical Approach: A convenience sample of all women on active duty in the Department of Defense in Region 3 (which includes Florida, Georgia and South Carolina) stationed at seven military installations will be asked to complete a questionnaire. A group assessment process will be utilized to gather data for the study. The investigator will personally administer the survey on the site of the installation at which subjects are assigned. Installation commanders will be contacted by phone and then with a follow-up letter and provided the purpose and methods of the research. They will be asked to contact staff within their commands who can identify all units with female soldiers and who would be helpful in facilitating the collection of data within these units. The units will then be contacted to arrange a date, time and place for the administration of the survey to the female soldiers within the unit.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Jun 94	**Protocol**	94-61	**Status**	Ongoing
Title:	Military Women's Perception of Sexual Harassment in the Military				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Dorothy Anderson, AN			**Facility:** Eisenhower Army Medical Center		
Department/Service: Nursing			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: To ascertain female soldiers perception of sexual harassment in the military.

Technical Approach: A personally administered questionnaire will be used to elicit the perceptions and personal experiences of officer and enlisted female soldiers concerning sexual harassment in the military. Three groups of female service members from health care, military police, and signal occupation specialties will be administered the questionnaire.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	08 Sep 94	**Protocol**	94-72	**Status**	Ongoing
Title:	Propofol for Induction of Anesthesia: Comparison of Fentanyl and Alfentanil on Cardiovascular Response to Laryngoscopy and Tracheal Intubation				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Antonio DeLaRosa, AN			**Facility:** Eisenhower Army Medical Center		
Department/Service: Nursing/Anesthesia			**Associate Investigators:** CPT Dan Hester, AN CPT Christoph Stouder, AN 1LT Kathleen Feeley, AN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To describe the difference in the cardiovascular response to laryngoscopy and tracheal intubation when using fentanyl or alfentanil, following a standard adult propofol induction.

Technical Approach: The study will examine only standard adult propofol inductions, defined as persons years of age of older, categorized as American Society of Anesthesiologists I or II, receiving nonemergent anesthetic induction with the agent propofol at standard weight doses. The study will further be limited to attenuating effects of fentanyl and alfentanil only on the blood pressure and heart rate, and will not be generalizable to other opiates. Student nurse anesthetists will be performing the laryngoscopy and tracheal intubation during this study.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol**	93-50	**Status:**	Terminate
Title:	Application of Ophthalmoscopic Examination Fluorescein Angiography in Early Diagnosis of Candida Endophthalmitis in Rabbits				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): LTC F. Ridgely Benton, Jr., LTC, MS		**Facility:** Eisenhower Army Medical Center			
Department/Service: Pathology		**Associate Investigators:** John F. Fisher, MD MAJ David Craft, MS MAJ Steve Tobias, VC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Study Objective: To assess the diagnostic efficacy of fluorescein labelled anti-Candida antibody to recognize infection by this organism at a clinically earlier stage than is now possible. It will look for early retinal lesions by using the tagged antibodies. This rabbit model has been used before and should be well suited for this type of study.

Technical Approach:

Number of animals used for reporting period: none

Progress: No progress due to one associate investigator leaving area.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-20	**Status:**	Ongoing
Title:	A Double-Blind Placebo Controlled, Parallel Study to Evaluate the Efficacy of Pepto-Bismol Liquid in the Treatment of Acute Diarrhea in Children Aged 3-6 Years				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Linda L. Fuqua, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Pediatrics			**Associate Investigators:** LTC Brenda Harper, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: This is a double-blind, placebo-controlled, parallel study to evaluate the efficacy of Pepto-Bismol liquid in the treatment of acute diarrhea in children aged 3-6 years.

Technical Approach: At the entry into the study, the degree of dehydration will be assessed clinically for each patient, and appropriate rehydration will be administered. Children with mild to moderate dehydration will be given non-rice ORS ad libitum over 4 to 6 hours. Children with severe dehydration will receive intravenous fluids as needed as well as ORS as tolerated ad libitum over 4 to 6 hours. Dosing with testing article will start after hydration has been completed. During the study, patients will receive a bland age-appropriate diet excluding lactose containing products. This will be followed by the child's regular diet as stools assume a normal consistency.

Progress:

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	92-43	**Status:**	Ongoing
Title:	The First Break Psychosis Study				

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Elaine Correnti, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Psychiatry & Neurology	**Associate Investigators:** Richard Borison, MD Manuel Casanova, MD Laura Davidson, PhD Bruce Diamond, MD Sahebarao P. Mohadik, MD Sukdeb Mukherjee, MD LTC Thomas Ralston, MC CPT Russell Scheffer, MC MAJ Neal Trent, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 94, Continue

Study Objective: To determine whether specific biological abnormalities previously found in chronic schizophrenic patients are present at the beginning of the illness and, if so, to examine their relations to clinical characteristics of the illness; and to examine whether selected clinical, historical, and biological measures are predictive of short-term clinical outcome in patients experiencing their first episode of psychosis.

Technical Approach: Patients will undergo comprehensive psychiatric, neuropsychological, and neurological examinations at baseline, and blood samples will be taken for determination of RBC activities of specific enzymes and measurement of tritiated imipramine binding in platelets. A skin biopsy will be performed to develop fibroblast cell lines in culture and examine whether fibroblasts from patients show the abnormalities of growth and morphology noted in studies of chronic schizophrenic patients.

Subjects enrolled to date: 25

Progress: Total of 25 subjects enrolled; 1 paper accepted for publication; 11 presentations at national meetings.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-13	**Status:**	Ongoing
Title:	Dexamethasone Augmentation in the Treatment of Major Depression				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Kerry Cleary, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** CPT Russell Scheffer, MC MAJ Michael Sokol, MC CPT Joseph Sutcliffe, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: This is a double-blind, placebo controlled study to test the hypothesis of decreased latency of response to traditional antidepressant medication with a one time dose of Dexamethasone as adjunct on initiation of pharmacotherapy Double Blind Placebo Control.

Technical Approach:

Number of subjects enrolled: 12

Progress: Nine additional patients enrolled in the study since last approval. This marked increase in enrollment is secondary to improved communication between investigators and inpatient/outpatient staff of the Psychiatry Department.

Problems encountered: No adverse side effects noted from medications administered since last approval. (One of initial three patients has allergic reaction consisting of rash due to Prozac. Medication discontinued and patient was taken off study).

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-37	**Status:**	Complete
Title:	The Relationship of Menstrual Phase to Presentation of Acute Psychiatric Treatment				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Miguel Oquendo, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry and Neurology			**Associate Investigators:** CPT John F. Mackey, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To evaluate the effect of menstrual cycle on the presentation of a patient for acute psychiatric evaluation.

Technical Approach: Subjects will be interviewed to include a review of systems, history of menstrual cycle. Epidemiologic data will then be evaluated to determine the characteristics of the patients considered.

Number of subjects enrolled for the reporting period: 60

Progress: This study is complete and has been presented at the Military Psychiatry Conference in San Antonio, Texas; EAMC Grand Rounds; and is pending submission for publication to the Journal of American Psychiatry Association.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-47	**Status:**	Ongoing
Title:	A Double-Blind, Placebo Controlled Exploratory Study of Sertraline in Adolescent Outpatients with Nondelusional Major Depressive Disorder.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Kerry Cleary, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Psychiatry and Neurology		**Associate Investigators:** MAJ Lawrence M. Correnti, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To compare the efficacy of sertraline HC1 (SER) in major depressive disorder without psychotic features with placebo in a double blind fashion using a population of thirty 12 to 18 year old adolescent outpatients.

Technical Approach: Various structured interviews and instruments will be used to insure that DSM-III-R criteria are met. A washout period will precede randomization.

Number of subjects enrolled for the reporting period:

Progress: Study ready for implementation after receiving medication and placebos. Principal investigator changed from Dr. Walter Duffy to Dr. Kerry Cleary.

Problems Encountered: The Diagnostic Interview Schedule for Children and Adolescents versions we have been given is not in working order. thus we are waiting on a working computer disk copy of it.

DETAIL SUMMARY SHEET

Date:	12 Aug 93	**Protocol**	93-57	**Status:**	Ongoing
Title:	Controls for the Neurological Evaluation Scale and the Premorbid Adjustment Scale				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Russell Scheffer, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry and Neurology			**Associate Investigators:** COL Celso Bolet, MC MAJ Elaine Correnti, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To provide normal and psychiatric control data for the NES and PAS. The NES and PAS are clinical evaluations that will be administered by one or more M.D.'s individually with the patient.

Technical Approach: Two groups of 50 subjects each will serve as normal and psychiatric controls for the NES and PAS to be used in comparison with the subjects enrolled in the FBPS.

Number of subjects enrolled for the reporting period: 50 normal controls; 16 psychiatric controls.

Progress: All 50 normal control subjects have been obtained; 16 of the 50 psychiatric controls have been obtained. Still obtaining psychiatric controls to complete study.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-15	**Status:**	Terminated
Title:	Felbamate Monotherapy in Newly Diagnosed Partial Epilepsy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Daniel P. Fosmire, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry and Neurolgoy			**Associate Investigators:** CPT Lawrence E. Clapp, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To determine efficacy of felbamate in preventing recurrent seizures in subjects with newly diagnosed partial onset epileptic seizures as compared to placebo.

Technical Approach:

Number of subjects enrolled for the reporting period: 0

Progress: This study has been terminated at the request of the drug company.

DETAIL SUMMARY SHEET

Date:	13 Jan 94	**Protocol**	94-36	**Status:**	Terminated
Title:	Open-Label, Follow-on Felbamate Therapy in Adult Subjects with Newly Diagnosed Partial Epilepsy				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Daniel Fosmire, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Psychiatry and Neurology				**Associate Investigators:** MAJ Lawrence Clapp, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:**	

Objective: To obtain additional safety information in subjects with newly diagnosed partial epilepsy who completed or had a seizure recurrence in Protocol 344 (DDEAMC 94-15).

Technical Approach: All patients in this protocol will receive open-label felbamate in doses of 2400-3600mg a day. Most of these patients will already be on protocol 344 receiving placebo.

Number of subjects enrolled for the reporting period: 0

Progress: This study has been terminated due to druge being withdrawn from the market.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-27	**Status:**	Ongoing
Title:	Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Military Personnel with Documented Recent HIV-Antibody Seroconversion - Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Lynn Levine, PhD, MPH			**Facility:** Eisenhower Army Medical Center		
Department/Service: Preventive Medicine			**Associate Investigators:** William Challenger, RN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: To determine specific factors that are associated with becoming infected with the Human Immunodeficiency Virus (HIV).

Technical Approach: Participants will use a laptop computer with headphones. The computer will play a recorded version of each question in which the participant will answer on the keyboard. The survey will contain many items, including very personal questions about sexual and other behaviors.

Progress: This study has not started yet.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	90-1	**Status:**	Ongoing
Title:	Technetium 99m Antimony Trisulfide Colloid for Investigation of Lymphatic Drainage				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Stephen G. Oswald, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology/Nuclear Medicine			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Jan 93, Oct 94, Continue		

Study Objective: To provide a radiopharmaceutical whereby lymphatic drainage may be characterized.

Technical Approach: Intradermal injection of radiolabeled colloidal particles with serial gamma camera images to evaluate lymphatic drainage.

Number of subjects enrolled to date: 4

Progress: Radiopharmaceutical temporarily unavailable due to change in manufacturer. Anticipate availability in not too distant future. Please keep protocol open.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	90-36	**Status:**	Ongoing
Title:	Treatment of Internal Contamination by Plutonium and Other Transuranic Elements with Two Investigational New Drugs (Ca-DTPA and Zn-DTPA)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): LTC Robert J. Kaminski, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** LTC Stephen G. Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Study Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Zn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

This is not an investigational study. This pharmaceutical is maintained in stock under and IND from Oak Ridge Laboratory for purposes of emergency treatment of internal contamination from nuclear materials accident. No patients treated this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-13	**Status:**	Complete
Title:	Scintigraphy of Tumors of Neuroectodermal Origin with 131-Iodine-Meta-iodobenzylguanibine Sulfate (131-I-MIBG)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): LTC Stephen G. Oswald, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** LTC Robert J. Kaminski, MC LTC James H. Corley, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue			

Study Objective: To provide a mechanism whereby this agent is available for use in diagnostic studies in patients undergoing evaluation of pheochromocytoma or staging of neuroblastoma.

Technical Approach: Intravenous injection of a radiopharmaceutical (MIBG) with subsequent gamma camera imaging.

Number of subjects enrolled: 3

Progress: One additional patient enrolled during past year. No adverse side effects or reactions noted. Study ongoing.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-39	**Status:**	Ongoing
Title:	Adrenal Imaging with 131-Iodine-6-Beta-Iodomethyl-Norcholesterol (NP-59)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Stephen G. Oswald, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology/Nuclear Medicine			**Associate Investigators:** LTC Robert J. Kaminski, MC CPT Daryl S. Moyer, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: To provide a mechanism whereby NP-59 is available for correlative adrenal imaging for patients with biochemically established ACTH-independent Cushing's syndrome, primary aldosteronism, or androgen excess states as well as characterization of the functional status of euadrenal masses.

Technical Approach: Intravenous injection of a radiopharmaceutical (NP-59) with subsequent gamma camera imaging.

Progress: No patients enrolled. Study ongoing. Wish to keep open to maintain access to investigational agent.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-28	**Status:**	Ongoing
Title:	Magnetic Resonance Imaging to Optimally Find and Accurately Define the Extent of Malignant Breast Lesions				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): George P. Forsyth, M.D.			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology			**Associate Investigators:** LTC Thomas Ralston, MC MAJ Sandra Pupa, MC MAJ Noel Haskins, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: To determine if magnetic resonance imaging (MRI) of the breast can provide a better means for detection of breast neoplasms (malignant tumors) than physical examination and/or plain film mammography. The purpose of this study is to also to determine how best to distinguish non-cancerous lesions from cancerous lesions within the breast.

Technical Approach: Perform magnetic resonance mammography on women with lesions that require biopsy. Such masses would be found by physical examination or detected by plain film mammograms. Only the single breast containing the lesion to be biopsied will be scanned. The results of this examination will be correlated with previous exams (mammography, ultrasound, etc.) and with pathologic specimens obtained from the breast biopsy.

Progress: Study not implented due to lack of funding.

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol**	94-48	**Status:**	Ongoing
Title:	Pelvic Pathology: Prospective Comparison of Computed Tomography, Ultrasound, and Magnetic Resonance Imaging				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): George P. Forsyth, M.D.		**Facility:** Eisenhower Army Medical Center			
Department/Service: Radiology		**Associate Investigators:** COL Gary Broadnax, MC LTC Stephen Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Study Objective: To demonstrate the effectiveness of 5th generation magnetic resonance imaging (MRI) versus computerized tomography (CT) and ultrasonography (US) and to determine if advances in magnetic resonance image quality have allowed MRI to surpass CT and US in the detection and definition of pelvic pathology in women.

Technical Approach: This study will evaluate female patients who meet clinical criteria for pelvic surgery. Imaging of the pelvis will be performed with three modalities (MRI, CT, US) and findings will be correlated with the histologic diagnosis. Oral barium contrast will be used in combination with intravenous gadolinium contrast to enhance pelvic organs during the high speed image acquisition now possible with 5th generation MRI equipment.

Progress: This study has not been implemented due to lack of funding.

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol**	85-5	**Status:**	Ongoing
Title:	Advanced Trauma Life Support Course				
Start Date:	Jan 85		**Est. Compl. Date:**		
Principal Investigator(s): MAJ Paul Lepage, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Clinical Investigation			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 93, Oct 94, Continue		

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The advanced trauma life support course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements as follows: Course Director (1 MC)
Course Administrator (MS)
Instructors (6 MC)
Logistical support (2 EM)
Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: Scheduled local ATLS course in March 1995.

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol**	90-32	**Status:**	Ongoing
Title:	Training General Surgery Residents Utilizing Goat and Pig Models				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Paul A. LePage, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Clinical Investigation			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 93, Oct 94, Continue		

Study Objective: To allow the practicing and refinement of surgical approaches and techniques on animal models prior to performing the same procedure in the human.

Progress: Two major Southeast regional courses were conducted to successfully train in new laparoscopic hernia and colorectal surgery to 38 students and weekly training to residents and staff. Also, nursing anesthesia students were trained on field Army anesthesia machines during these sessions. Operating room nurses were trained on laproscopic techniques and a multidisciplined laboratory training session for gynecologists and general surgeons in gastro/enterology laparascopy.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-59	**Status:**	Terminated
Title:	Use of the Rat Model for Teaching and Practicing Microvascular Surgical Technique				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Brian K. Barnard,			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			**Associate Investigators:** Orthopedic Residents		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Nov 93 continue		

Study Objective: To utilize the rat model for the practice and teaching of microvascular surgical techniques.

Technical Approach: Training procedures include end-to-end, end-to-side, and side-to-side anastomosis of the femoral artery and vein, as well as, interpositional vein grafting.

Progress: Terminated due to ETS of principal investigator.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-81	**Status:**	Ongoing
Title:	Evaluation of the Current Routine Post Op Feeding Regimens				
Start Date:			**Est. Compl. Date:**	Dec 93	
Principal Investigator(s): CPT M. Brian Harkins, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** MAJ Robert G. Martindale, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Jan 93, Oct 94, Continue		

Study Objective: To determine if patients are able to tolerate a regular diet rather than clear liquids as their first P.O. intake following intraabdominal surgery.

Technical Approach: Randomized patients to alternate diets.

Number of subjects enrolled to date: approximately 125-150

Progress: Study ongoing, data collection continuing.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	92-4	**Status:**	Ongoing
Title:	The Effect of Pentoxifyline vs Allopurinol on Sigmoid Mucosal Ischemia During Abdominal Aortic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT William C. Calton, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** MAJ Robert G. Martindale, MC LTC Manuel F. Ramirez, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Jan 93, Oct 94, Continue		

Study Objective: This study will make considerable use of a new noninvasive technique to measure the adequacy of tissue oxygenation called tonometry.

Technical Approach: Tonometry relies upon the fact that CO2 is freely permeable between the lumen, luminal fluid and superficial layer of the mucosa. By measuring CO2 in the luminal fluid and simultaneously measuring arterial blood gases, mucosal pH can be calculated using the Henderson-Hasselbalch equation. The validity and safety of this technique has now been substantiated in several studies.

Progress: Project on hold due to lack of technical assistance and equipment limitations. Protocol will continue when research nurse is available.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	92-13	**Status:**	Closed
Title:	The Effect of IV Pentoxifylline on Endotoxin Mediated Small Bowel Mucosal Ischemia Using the Pig Model				
Start Date:			**Est. Compl. Date:**	Dec 93	
Principal Investigator(s): CPT William C. Calton, Jr., MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** MAJ Robert G. Martindale, MC LTC Michael P. Byrne, MC MAJ David Turgeon, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Resuts:**		

Study Objective: To determine if pentoxifylline can attenuate the splanchnic vasoconstriction seen with endotoxin.

Technical Approach:

Progress: No progress since last reporting period. Principal investigator has transferred.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	92-26	**Status:**	Terminated
Title:	The Effects of Somatostatin Analog (Octreotide Acetate) on Wound Healing in the Mouse Model				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert G. Martindale, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** MAJ Donald E. Sutherland, MS CPT William Calton, Jr, MC CPT Sam Miller, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93		

Study Objective: To determine if the somatostatin analog affects wound healing.

Technical Approach:

Progress:

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	92-27	**Status:**	Ongoing
Title:	Natural History of Free Gallstones Within the Peritoneum in a Rabbit Model and Mouse Model				
Start Date:			**Est. Compl. Date:**	Dec 93	
Principal Investigator(s): CPT Ray Workman, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** LTC Michael Byrne, MC MAJ Robert G. Martindale, MC Thomas R. Gadacz, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93, Oct 94, Continue		

Study Objective: To determine the physiologic response to free gallstones within the peritoneum in the rabbit and mouse models.

Technical Approach:

Progress: Have sacrificed nine rabbits with last three due for sacrifice on 29 July 1994. Pathology results will follow final group. Due for completion July 1994.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	**Protocol**	92-52	**Status:**	Complete
Title:	Laparoscopic Appendectomy vs Standard Appendectomy				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Thomas Taylor, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/General Surgery		**Associate Investigators:** MAJ Victor L. Modesto, MC MAJ Paul A. LePage, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Aug 93 Continue			

Study Objective: To compare hospital stay, amount of post-operative pain medications, amount of post-operative complications such as wound infection and abscess formation, and the percentage of false positives to that of open appendectomy. We also wish to become proficient in the art of laparoscopic appendectomy.

Technical Approach: Open appendectomy will be performed in the standard fashion utilizing a Rockey Davis incision. An extension of this incision may be utilized as deemed necessary by the senior surgeon performing the case. All open appendectomies will undergo irrigation of the pelvis in the reverse trendelenburg position.

Subjects enrolled to date: 17

Progress: Study complete.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-4	**Status:**	Ongoing
Title:	The Effect of Early Enteral Feeding on Patients Undergoing Abdominal Aortic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT William C. Calton, Jr., MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** MAJ Robert G. Martindale, MC MAJ Donald E. Sutherland, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Study Objective: To evaluate the effect of early enteral feeding on outcome, nutritional parameters and wound healing in patients undergoing abdominal aortic surgery.

Technical Approach:

Number of subjects enrolled for reporting period: 10

Progress: Still accumulating data on vascular patients (aortic cases). Principal Investigator has departed but protocol will continue under supervision of C, Vascular Surgery.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-35	**Status:**	Ongoing
Title:	Effects of Somatostatin Analog (Octreotide Acetate) on Wound Healing in Bowel and Gastric Anastomosis in the Rat Model				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Samuel K. Miller, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** MAJ Robert G. Martindale, MC CPT William Calton Jr, MC MAJ Donald Sutherland, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93, Oct 94, Continue		

Objective: To determine the effects of somatostatin analog (Octreotide acetate) on bowel and gastric anastomosis.

Technical Approach:

Progress: Protocol complete but PI requests 100 additional rats to add a fifth group to answer questions about interaction of octreotide and steroids on bowel wound healing.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-38	**Status:**	Complete
Title:	Biomechanical Analysis: Multiple Lag Screw vs Plate Fixation of the Distal Fibula				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Paul J. Cutting, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			**Associate Investigators:** CPT Jeffrey M. Oettinger, MC CPT Francis K. Moll, MC LTC Joseph M. Erpelding, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To analyze rotational strengths of multiple lag screw vs plate fixation.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Bench testing (torsional) completed at Redstone Arsenal, Alabama in May 1994. Submitted for publication.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-42	**Status:**	Ongoing
Title:	Mechanical Peritoneal Retraction Laparoscopic Surgery				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Paul A. LePage, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** COL Sidney R. Steinberg, MC LTC David E. Rivera, MC LTC Manuel F. Ramirez, MC General Surgery Service LTC Kevin C. Kelley, MC OB-GYN Service			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To demonstrate whether the Laparolift System provides equivalent or better exposure than conventional pneumoperitoneum.

Technical Approach:

Number of subjects enrolled for reporting period: None

Progress: Progress is help waiting for MEDCASE approval for purchase of laprolift device

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-61	**Status:**	Ongoing
Title:	The Effect of Vitamin A on the Steroid Induced Defect in Wound Healing: A Time Course Study in Mice				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Patricia S. Greatorex, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, M.D., Ph.D. COL Peter M. Barcia, MC MAJ Donald Sutherland, MS MAJ Steven Tobias, DVM		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To evaluate the potential beneficial effect of Vitamin A in reversing the detrimental effect steroids have on wound healing, examine in chronological sequence the inhibitory effect of corticosteroids on wound healing with and without the addition of Vitamin A, and create a time response curve that will demonstrate when steroids have their peak inhibitory effect and what role Vitamin A has in this time sequence.

Technical Approach:

Number of animals used for reporting period: None

Progress: Animal portion of protocol completed at Tripler Army Medical Center. PTFE specimens were processed in HCl. Measurement of collagen still needs to be completed.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-63	**Status:**	Ongoing
Title:	The Adverse Effects of Octreotide on Wound Healing in Rats Study in Mice				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): CPT Brad E. Waddell, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery				**Associate Investigators:** Robert G. Martindale, M.D., Ph.D. CPT Cheuk Y. Hong, MC MAJ Steven Tobias, VC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Oct 94, Continue	

Objective: To determine the nature and extent of octreotide's adverse effects on wound healing.

Technical Approach:

Number of animals used for reporting period: none

Progress:

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-65	**Status:**	Ongoing
Title:	The Use of 1% Lidocaine With/Without Epinephrine in Breast Biopsy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Samuel Miller, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** CPT Darren Chapman, MC CPT Scott Needham, MC MAJ Paul A. Lepage, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To determine complication rates in breast biopsies as influenced by the use of local anesthetic.

Technical Approach:

Number of subjects enrolled for reporting period: 200

Progress: Protocol still in data collection phase.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	93-67	**Status:**	Completed
Title:	Parachuting Injuries: A Medical Analysis of an Airborne Operation				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT John F. Kragh, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To outline variables assocaited with soldier injuries as a result of an airborne assault and to enhance physician understanding of parachute injuries to enable proactive prevention and improved medical and non-medical support.

Technical Approach: A retrospective analysis of a battalion sized airborne assault was done through a review of ranger documents, analysis of photographs, and conduction of interviews.

Number of subjects enrolled for reporting period: 475 male rangers

Progress: Study complete.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-14	**Status:**	Ongoing
Title:	A Randomized, Open-Label, Parallel Group Comparison of the Safety and Efficacy of Lovenox (Enoxaparin) Injection vs Adjusted Dose Coumadin (Warfarin) in the Prevention of Thromboembolic Disease Following Hip Replacement Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Joseph M. Erpelding, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** CPT Paul Benfanti, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To evaluate the safety and efficacy of Lovenox Injection versus adjusted dose Coumadin in the prevention of clinically significant thromboembolic disease following elective total hip replacement during hospitalization and to determine the medium term incidence (three months post-hospital discharge) of morbidity and mortality resulting from thromboembolic disease following elective total hip replacement surgery in patients treated with Lovenox injection versus adjusted dose Coumadin.

Technical Approach: This protocol study is divided into two phases; an inpatient period following surgery, not to exceed 14 days, and an outpatient followup period of three months. When the surgeon is satisfied that hemostasis has been achieved, and within 24 hours post-operatively, patients will begin their randomly assigned treatment of either Lovenox injection, 30 mg BID, or adjusted dose Coumadin until hospital discharge, but not to exceed a maximum of fourteen days. All patients will return to the investigator for followup examination at approximately six and twelve weeks post-hospital discharge.

Number of subjects enrolled for reporting period: 18

Progress: Thus far there have been 18 patients enrolled for this study. Our study goal is 20 patients.

Adverse Reactions: One patient developed post-op hematoma and was withdrawn from study.

Problems Encountered: None, except between the ward and pharmacy getting the medication to the ward.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-29	**Status:**	Terminated
Title:	A Double-Blind Comparison of the Efficacy and Safety of Extended Outpatient Treatment with Subcutaneous Normiflo Versus Placebo for the Prevention of Venous Thromboembolism in Patients After Hip or Knee Replacement Surgery				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): LTC Joseph M. Erpelding, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopaedics		**Associate Investigators:** CPT Joseph Legan, MC MAJ John Kragh, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To compare the safety and efficacy of extended outpatient treatment with Normiflo versus placebo for the prevention of venous thromboembolism (DVT/PE) following hip or knee replacement surgery.

Technical Approach: The study will consist of two parts: (a) an open label, uncontrolled portion of the study in which all patients will receive subcutaneous Normiflo injections BID; (b) double blind, controlled in which patients will be randomized to receive once daily subcutaneous injections of either Normiflo or placebo. Randomization will be stratified by investigational site, by type of surgery (i.e., hip vs. knee), and by whether or not a patient has a history of previous DVT/PE. Patients will have completed the study at the time of the final contact which is to occur 10 weeks after surgery (four weeks after the last scheduled dose of study medication).

Number of subjects enrolled for reporting period:

Progress: No progress to report.

Problems Encountered: No nursing support for home visits.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-30	**Status:**	Ongoing
Title:	Group Screening of Genetic Alterations and Blood Markers in Breast Tumor Patients				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Robert S. Thomas, Jr., MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Charles Cheng Henry Chuang James McPherson, III		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To obtain statistical correlations among genetic alterations, disease status and changes in blood tumor marker of breast cancer patients.

Technical Approach: Collect samples from tissues and blood samples from normal and breast cancer patients of different disease status. Data will be correlated to patient disease stages, age and metastatic conditions and statistical analysis to determine differences among the groups identified.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-31	**Status:**	Ongoing
Title:	Breast Cyst Fluid Content of Interleukin-6, Prolactin and Progesterone and Their Effects on Co-Cultured Breast Tissues				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Robert S. Thomas, Jr., MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Carol Lapp Kenna Given, MD			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To develop a diagnostic tool which could improve the possible predictability of future outcomes, so that women with low risk would be reassured, and women at high risk could be vigilant. The clinical aspect of the study will classify breast cyst fluid on the basis of its ionic composition and attempt to correlate this parameter with the fluid concentrates of prolactin, progesterone and/or interleukin-6, with the goal of discovering a more accurate marker of increased apocrine activity. The laboratory aspect involves examining paracrine responses of the breast epithelial and fibroblastic cell types, to better understand how they influence each other, and how each cell type is influenced separately and in concert.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-32	**Status:**	Ongoing
Title:	Segregation and Sequence Analysis of a Candidate Breast Cancer Gene in Affected Families				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Robert S. Thomas, Jr., MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Nurul Sarkan, MD, MCG Terry Spinkle, MD, MCG Francis Chandler, MD, MCG Aquan Kripamoy, MD, MCG Li Yin-Xwing, MD, MCG			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To evaluate the exact location of the CNP gene in relation to the other well studied closely linked markers.

Technical Approach: Patient participation is limited to donating tissue being removed for clinical indications. If positive cases are found, family members will be invited to donate blood by venipuncture.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	13 Jan 94	**Protocol**	94-37	**Status:**	Ongoing
Title:	Translocation Bacteremia from the Lung Caused by Volume Ventilation in Sus Scrofa				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Thomas B. Taylor, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To look at the effects caused by over insufflating the lungs as may inadvertently happen during surgery or other procedures requiring general anesthesia.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Control group of animals completed. No significant problems have been encountered.

DETAIL SUMMARY SHEET

Date:	10 Mar 94	**Protocol**	94-42	**Status:**	Ongoing
Title:	A Randomized Study to Compare the Safety and Efficacy of Various User-Convenient Dosing Regimens of Procrit (Epoetin Alfa) in Subjects Undergoing Major Orthopaedic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Joseph Erpelding, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** MAJ John Kragh, MC CPT Joseph Legan, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To compare the safety and efficacy of various user-convenient dosing regimens of PROCRIT in subjects undergoing major orthopaedic surgery (hip or knee replacement) to determine if a more user-convenient dosing regimen with lower total doses of PROCRIT produces an erythropoietic response comparable to PROCRIT 300 U/kg x 15 doses.

Technical Approach: One hundred thirty subjects scheduled for major orthopaedic surgery involving hip or knee replacement will be enrolled in this study. Subjects must be unwilling or unable to participate in an autologous blood predeposit program. As subject qualify for the study, they will be assigned to one of four treatment groups. All subjects will receive an oral iron supplement provided by R.W. Johnson PRI, throughout the course of treatment, starting at least on the first day of study medication. Safety evaluations will be made by clinical laboratory tests, vital sign measurements, and by the incidence and severity of adverse events. In addition, a complete physical examination will be performed prestudy and upon completion.

Number of subjects enrolled for reporting period: 2

Progress: All drugs, supplies and personnel are in place. Have randomized two patients.

Problems Encountered: The inclusion hemoglobin, 10-13, is extremely difficult to meet. There have been 35 patients screened.

DETAIL SUMMARY SHEET

Date:	10 Mar 94	**Protocol**	94-43	**Status:**	Ongoing
Title:	Gut Colonization as a Predictor of Nosocomial ICU Infections				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Thomas Knuth, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To document the presence of pathogenic organisms in gastric aspirates and to determine the relationship of these organisms to subsequent nosocomial infections. This study will also document multiple successive cultures, instead of a single culture, from individual patients so that the timing of colonization to nosocomial infection can be determined.

Technical Approach:

Number of subjects enrolled for reporting period: 10

Progress: We began collecting data in July 1994. At the present time we have entered approximately 2 patient days of data per day.

Problems Encountered: Microbiology will only support 2 cultures/day. At this rate, the study will take 2 years, if there are no breaks.

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol**	94-44	**Status:**	Ongoing
Title:	Kinematic Effect of Twisting on Anterior Cruciate Ligament Patellar Bone Tendon-Bone Grafts in Anterior Cruciate Ligament Reconstruction in Cadaveric Knees				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Francis Moll, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** CPT Richard Pope, MC MAJ Dean Taylor, MC COL Dennis Runyan, DE		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To evaluate the possible beneficial and/or deleterious effect graft rotation has on the kinematics of the knee in ACL reconstruction.

Technical Approach: An in vitro study utilizing a previously described cadaver model for knee kinematics will examine the effect of twist on a patellar BIB graft in ACL reconstruction. A fresh frozen cadaver lower extremity with no recorded or demonstrable musculoskeletal disease will be used as a knee model for ACL reconstruction.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	12 May 94	**Protocol**	94-60	**Status:**	Ongoing
Title:	The Biochemistry and Physiology of Wound Healing in Association with Synthetic Materials Used for Temporary Closure of Abdominal Wall in the Rat Model				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): COL Sidney R. Steinberg, MC R. Martindale, M.D., PhD, MCG		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** X.X. Gao, PhD, MCG T.R. Howdieshell, MD, MCG COL Manual Ramirez, MC MAJ David Craft, MS M. Hawkins, MD, MCG MAJ Steven Tobias, MS, DVM Norma Best, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 94, Continue			

Objective: To evaluate the effectiveness and utility of synthetic materials in emergent abdominal wall closure, and to determine and design the optimal material to be used for emergent closures.

Technical Approach: This protocol will also attempt to address the mechanisms of altered wound healing noted when using synthetic material. Post-operative pain will be monitored by behavioral criteria with analgesics administered as required.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Jun 94	**Protocol**	94-64	**Status:**	Ongoing
Title:	The Application of Advanced Telemedicine and Related Off-the-Shelf Medical Technology to Improve Overall Healthcare Delivery for Deployed Military Women				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Thomas E. Knuth, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To demonstrate use of advanced medical and communications technologies to project medical subspecialty expertise to remote locations; to define technologies and connectivity required to operate telemedicine from remote locations; and to determine physician and patient acceptance of advanced technologies.

Technical Approach: Advanced digital compression-decompression devices and connectivity links and emphasize economical, readily available commercial phone lines. After each consultation, medical care providers from both sites and the patient will be asked to fill out satisfaction surveys which will be used to assess acceptance of the technology as well as psychological impact, especially relevant to deployment of women.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	11 Aug 94	**Protocol**	94-66	**Status:**	Ongoing
Title:	Treatment of Thoracolumbar Burst Fractures. A Prospective, Randomized Trial				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Alfred E. Geissele, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** LTC Joseph M. Erpelding, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To compare the outcomes of non-operative versus operative treatment of thoracolumbar burst fractures. This study will also evaluate and compare differences in clinical, radiographic, and functional outcomes between the two treatments.

Technical Approach: Patients will be enrolled and randomized without regard to loss of anterior vertebral body height, segmental kyphosis, or degree of canal compromise. Prior to entry, patients will undergo AP and lateral radiographs of the thoracolumbar spine and a CT evaluation of the canal at the level of the fracture. A history of premorbid back pain or injuries will be asked for as well as a pain drawing and a visual analogue pain rating, a Denis pain and work scale, and an Oswestry Disability Questionnaire.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	11 Aug 94	**Protocol**	94-69	**Status:**	Ongoing
Title:	Migration of Prolene Mesh Following Laparoscopic Preperitoneal Hernia Repair				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): COL Sidney Steinberg, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Lisa Bromberger, RN CPT Samuel Miller, MC Dr. Robert Martindale, MCG MAJ Noel Haskins, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To determine how much and when the prolene mesh migrates from the abdominal wall following a laparoscopic preperitoneal hernia repair.

Technical Approach: The study will be such that during the preperitoneal hernia repair the prolene mesh, with a fine radiopaque suture material woven into the perimeter of the material, will be placed in the standard fashion. Immediately upon complete of the hernia repair, while the patient is still under anesthesia, a flat plate of the abdomen will be taken. The x-ray will then be read by the operating surgeon, principal investigator, and the faculty radiologist to evaluate location and position of marlex mesh. At three months the patient will be asked to return to the hospital for one additional abdominal x-ray in the supine position. Those x-rays will then be compared for migration of mesh. The x-ray will be coned down as much as possible to the area of interest.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Sep 94	**Protocol**	94-71	**Status:**	Ongoing
Title:	The Effect of Intraoperative Hip Position on Maintenance of Lumbar Lordosis.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): CPT Paul L. Benfanti, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopaedics		**Associate Investigators:** MAJ Alfred E. Geissele, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To determine the effect of hip position on maintenance of lumbar lordosis during positioning on the Wilson frame.

Technical Approach: There will be three limbs to this study. The first is retrospective and radiographic data review on patients undergoing lumbar surgery. The second limb will involve obtaining intraoperative x-rays on patients undergoing lumbar discectomy or fusion on the Wilson frame with their hips in the flexed and extended position. Normally two localizing x-rays are obtained with the hip position dictated by the type of surgery (discectomy = flexed; fusion = extended). For the purposes of this study, the first x-ray would be taken in the opposite position, the patient repositioned, and the procedure would continue with no additional radiographs. The third limb of the study will involve obtaining the same radiographs on unanesthetized volunteers with no history of low back pain within the preceding twelve months. This would permit the limitations of the first two limbs to be overcome, but would involve some x-ray exposure.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	08 Sep 94	**Protocol**	94-80	**Status:**	Ongoing
Title:	The Use of Vitamin A in the Reversal of Corticosteroid Induced Defects in Wound Healing (Rattus Norvegius)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert Martindale, M.D.		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** COL Sidney Steinberg, MC K. Jeffery, MD, MCG MAJ Brad Waddell, MC MAJ David Craft, MS CPT Kim Vlach, MS, DVM SPC Demetrius Collins, Vet Technician			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To address the effectiveness of Vitamin A in reversing the detrimental effects of steroids on wound and tissue healing. The dose and duration at which Vitamin A accomplishes this will also be evaluated.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-27	**Status:**	Ongoing
Title:	SWOG 8809 - A Phase III Study of Alpha-interferon Consolidation Following Chemotherapy with Promace-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 94, continue			

Study Objective: To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy-radiation therapy, to those who receive induction therapy alone. To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MCPP (day 1-8). To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: No problems encountered during this period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-29	**Status:**	Ongoing
Title:	SWOG 8854 (ECOG 1189, NCCTG 898051) - Prognostic Value of Cytometry Measurements of Breast Cancer DNA from Postmenopausal Patients with Involved Nodes and Receptor Positive Tumors: A Comparison Protocol to SWOG 8814				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** MAJ Karen Bowen, MC LTC Robert D. Ranlett, MS LTC Arthur Wozniak, MS MAJ Don Shaffer, MC LTC Charles T. Thornsvard, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG 8814. To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-30	**Status:**	Ongoing
Title:	SWOG 8814 (ECOG-4188, NCCTG-883051) - Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Nodes and Positive Receptors				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** LTC Robert D. Ranlett, MS LTC Arthur Wozniak, MS MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 2

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-31	**Status:**	Ongoing
Title:	SWOG 8897 (EST-2188, CALGB-8897, INT0102) - Phase III Comparison of Adjuvant Chemotherapy With or Without Endocrine Therapy in High-risk, Node Negative Breast Cancer Patients, and a Natural History Follow-up Study in Low-risk, Node Negative Patients				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert F. Krywicki, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology				**Associate Investigators:** MAJ Karen Bowen, MC LTC Robert D. Ranlett, MS LTC Arthur Wozniak, MS MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Feb 94, Continue	

Study Objective: To compare disease-free survival (DFS) and overall survival (S) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. To compare the relative toxicity of the therapies. To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. To evaluate the DFS and S of low risk invasive breast cancer determined by receptor status, tumor size and S phase treated by local therapy only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-34	**Status:**	Closed
Title:	SWOG 8931 (EST-3189, INT-0108) - Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node Positive Breast Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** MAJ Karen Bowen, MC COL Paulino O. Vasallo, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Objective: To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16-week multi-drug chemotherapy regimen. To compare toxicities of adjuvant CAF and a 16-week multi-drug regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-35	**Status:**	Ongoing
Title:	SWOG 8947 - Central lymphoma serum repository protocol. (Companion study to SWOG 8516, 8736, 8809 or 8816)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** LTC Rodney G. Day, MS LTC Stephen Oswald, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC COL Charles T. Thornsvard, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. To utilize the SWOG database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Blood sample will be drawn and shipped to the Serum Repository Laboratory for testing.

Number of subjects enrolled for reporting period: 0

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol**	91-41	**Status:**	Ongoing
Title:	SWOG 8736 - Treatment of localized non-Hodgkin's lymphoma: Comparison of chemotherapy (CHOP) to chemotherapy plus radiation therapy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: The primary study objective is to evaluate, in a cooperative group setting, the difference in survival, time to treatment failure and toxicity of two curative approaches to the treatment of patients with localized, intermediate or high grade, non-Hodgkin's lymphoma. The first treatment approach is chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) for eight cycles. The second uses CHOP for three cycles followed by involved field radiation therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 0

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol**	91-50	**Status:**	Closed
Title:	SWOG 8851 - Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node-positive, Receptor-positive Breast Cancer -- Intergroup				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** LTC Robert D. Ranlett, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (X + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. To compare the relative toxicities of these 3 regimens. To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-53	**Status:**	Ongoing
Title:	SWOG 8952 - Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid				
Start Date:		Est. Compl. Date:			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		Facility: Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		Associate Investigators: COL Jayanti K. Sen, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC			
Key Words:					
Accumulative MEDCASE Cost:		Periodic Review Results: Feb 94, Continue			

Study Objective: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	91-55	**Status:**	Ongoing
Title:	SWOG 9013 - A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery Alone for Patients with Local Regional Disease. Phase III Intergroup				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** COL Paulino O. Vasallo, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Mar 93, Feb 94, Continue		

Study Objective: To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, versus pre- and post-operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. To compare the local and distinct control rates with the two approaches and to define the pattern of failure. To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol**	91-68	**Status:**	Closed
Title:	SWOG 9028 - A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma. Comparison of 1) VAD to VAD/Verapamil/Quinine for Induction with Crossover to VAD/Verapamil/Quinine for VAD Induction Failures; 2) Alpha-2-b Interferon Plus Prednisone for Remission Maintenance				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapamil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. The effectiveness of VAD plus verapamil and quinine for non-responders and progressors of the VAD induction regimen will also be investigated. This will be evaluated in terms of relapse-free and overall survival and P-glycoprotein expression prior to therapy and at the end of induction therapy in relation to the induction therapy arm. To compare the value of Intron-A (alpha-2b interferon) maintenance versus Intron-A plus prednisone for patients proven to achieve at least partial remission (50% tumor regression). The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization to maintenance therapy. The time from relapse to death will also be assessed in relation to objectives 1 and 2. To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma via serial studies of bone marrow myeloma cells by immunophenotyping. These immunophenotypic markers will be assessed prior to therapy, after completion of induction chemotherapy and/or at the time of relapse and related to clinical findings of drug-sensitivity or resistance to the treatment administered. Moreover, the expression of P-glycoprotein will be related to relapse free and overall survival and to whether the patient receives chemosensitizers along with VAD chemotherapy to determine whether the sensitizers inhibited the development of P-glycoprotein expression. To evaluate the relationship between the magnitude of cytoreduction and survival. To evaluate the significance of pretreatment serum lactic dehydrogenase (LDH) as a marker for aggressive myeloma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 1

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	91-69	**Status:**	Ongoing
Title:	SWOG 9111 (EST-1690) - Post-operative Adjuvant Interferon Alpha-2 in Resected High Risk Primary and Regionally Metastatic Melanoma, Intergroup				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alpha-2 as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. To evaluate the efficacy and tolerance of long-term interferon alpha-2 at 3 MU/d (Sc TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: 0

Progress: No patients enrolled to date.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	91-70	**Status:**	Closed
Title:	SWOG 9125 - A Phase II Trial of CVAD/Verapamil/Quinine for Treatment of Non-Hodgkin's Lymphoma				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) when administered in combination with chemosensitizers (verapamil and quinine) which are intended to block the emergence of multidrug resistance in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of CVAD plus verapamil and quinine will be based on the estimate of the complete response rate and the time to treatment failure. To assess the toxicities and side effects associated with the CVAD regimen when combined with verapamil and quinine. A secondary objective is to further investigate the utility of the proliferative rate (determined by Ki-67 monoclonal antibody), the importance of cell-cell recognition molecules (using a panel of monoclonal antibodies specific for several cell recognition antigens), the role of host response (using markers of tumor infiltrating T-cells in B-cell lymphomas) and the value of detectable levels of P-glycoprotein as prognostic indicators of outcome (see companions study SWOG 8819). A secondary objective is to further utilize the central serum repository enabling clinicopathologic correlations with the results of studies on the material collected (see companion study SWOG 8947).

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: No patients enrolled to date.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-6	**Status:**	Ongoing
Title:	SWOG 9008 - Trial of Adjuvant Chemoirradiation after Gastric Reaction for Adenocarcinoma, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** LTC Paulino O. Vasallo, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, M LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoradiation after gastric resection.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: No patients enrolled to date.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-7	**Status:**	Ongoing
Title:	SWOG 9108 (CALGB-9011, NCIC-CTGCL.1) - A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs (fludarabine) Phosphate Plus Chlorambucil in Previously Untreated B-cell Chronic Lymphocytic Leukemia				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert F. Krywicki, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology				**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Result:** Feb 93, Feb 94, Continue	

Study Objective: 1) To compare in previously untreated CLL patients the response rates and progression free survival with the following three therapeutic regimens: i) fludarabine phosphate, ii) chlorambucil and iii) fludarabine phosphate + chlorambucil. 2) To determine whether the quality of life (need for transfusions, incidence of infections, and performance status) is superior using any of the three regimens. 3) To determine whether these two drugs (fludarabine phosphate and chlorambucil) are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they are initially randomized.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: 0

Progress: No problems encountered this reporting period.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-37	**Status:**	Ongoing
Title:	SWOG 9007 - Cytogenic Studies in Leukemia Patients, Ancillary				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** MAJ Don Shaffer, MC COL Jayanti K. Sen, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled during this reporting period: 1

Progress: One patient expired during this reporting period.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-38	**Status:**	Ongoing
Title:	SWOG 9031 - A Double-blind Placebo Controlled Trial of Daunomycin and Cytosine Arabinoside With or Without rhG-CSF in Elderly Patients with Acute Myeloid Leukemia, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** MAJ Don Shaffer, MC COL Jayanti K. Sen, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare the complete response rates and durations of survival in patients aged 65 or older with acute myeloid leukemia (AML) when treated with standard doses of cytosine arabinoside (Ara-C) and daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To assess the frequency and severity of toxicities of the two treatment regimens. To compare the duration of neutropenia and thrombocytopenia; the total number of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-39	**Status:**	Ongoing
Title:	SWOG 9139 - Adjuvant Therapy of Primary Osteogenic Sarcoma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** MAJ Don Shaffer, MC COL Jayanti K. Sen, MC LTC Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To estimate the time to treatment failure and survival rate of the three drug combination adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. To evaluate histopathologic tumor necrosis following preoperative adriamycin, cisplatin, and ifosfamide. To assess the feasibility of determining histopathologic tumor necrosis in a cooperative e group setting. To assess the influence of clinical prognostic variables on disease outcome. To assess the toxicity of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-49	**Status:**	Ongoing
Title:	SWOG 9019 - A Phase III, Randomized Prospective Comparison Between Chemotherapy Plus Radiotherapy and the Same Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIA (Positive Mediastinal Nodes) and Selected Stage IIIB (No Malignant Effusion) Non-small Cell Lung Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Robert D. Ranlett, MC COL Charles T. Thornsvard, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (Ne-positive) and selected IIIb non-small cell lung cancer. To evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: 0

Progress: One patient expired during this reporting period.

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol**	92-50	**Status:**	Ongoing
Title:	SWOG 9035 - Randomized Trial of Adjuvant Immunotherapy with an Allogenic Melanoma Vaccine for Patients with Intermediate Thickness Node Negative Malignant Melanoma (T3NOMO)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/ Pathology			**Associate Investigators:** MAJ Don Shaffer, MC COL Paulino D. Vasallo, MC COl Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare disease-free survival and overall survival between patients with T3NOMO malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3NOMO malignant melanoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: 1

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol**	92-68	**Status:**	Closed
Title:	SWOG 8955 - Treatment of Stage D, Hormone Refractory Carcinoma of the Prostate with 5-Fluorouracil and Roferon-A, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Karen Bowen, MC MAJ Don Shaffer, MC LTC Stephen Oswald, MC COL Charles T. Thornsvard, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with F-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol**	92-69	**Status:**	Ongoing
Title:	SWOG 9059 - Phase III Comparison of Standard Radiotherapy *versus* Radiotherapy Plus Simultaneous Cisplatin, *versus* Split-Course Radiotherapy Plus Simultaneous Cisplatin and 5-Fluorouracil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC COL Charles T. Thornsvard, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare the effectiveness of standard radiation therapy alone to radiation therapy and simultaneous chemotherapy with cisplatin to split-course radiation therapy with cisplatin and 5-fluorouracil infusion in patients with unresectable Stage III and IV squamous cell carcinoma of the head and neck. Endpoints will include complete response rate, time to treatment failure, and overall survival. To compare the relative toxicities of these three treatment arms in this patient population. To compare patterns of relapse or treatment failure among these regimens. To further assess the role, timing, and success of surgery in patients achieving a response to non-operative therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: One patient expired during this reporting period.

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol**	92-70	**Status:**	Ongoing
Title:	SWOG 9129 - Phase III Randomized Study of All-Trans Retinoic Acid *versus* Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC COL Charles T. Thornsvard, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in Patients with previously untreated APL. To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as induction therapy in APL. To determine the value of maintenance therapy with TRA.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting periode: 0

Progress: One patient expired during this reporting period.

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol**	92-71	**Status:**	Closed (temporary)
Title:	SWOG 9150 - Evaluation of Topotecan in Gastric Cancer, Phase II				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** COL Jayanti K. Sen, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC COL Charles T. Thornsvard, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Hold			

Study Objective: To evaluate the response rate of gastric carcinoma treated with topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-7	**Status:**	Closed
Title:	SWOG 9104 - Evaluation of Doxorubicin/Vinblastine Combined with Inhibitors (Trifluoperazine/Verapamil) of P-Glycoprotein in Patients with Advanced Renal Cell Carcinoma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective:

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered to date.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-8	**Status:**	Ongoing
Title:	SWOG 9133 - Randomized Trial of Subtotal Nodal Irradiation versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC LTC Stephen Oswald, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare the ability of two treatment regimens (radiation therapy alone or radiation plus chemotherapy), one of which will be chosen to treat the cancer. This study will also determine whether these treatments have any effect on the patients disease free survival, and whether the effects of treatment are different for different people based on age, gender, type of disease and number of disease sites.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-9	**Status:**	Ongoing
Title:	SWOG 9148 - A Phase II Study of Cisplatin Preceded by a 12-Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (ARA-C) for Patients with Untreated Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert F. Krywicki, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology				**Associate Investigators:** MAJ Karen Bowen, MC MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti Sen, MC LTC Stephen Oswald, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Feb 93, Feb 94, Continue	

Study Objective: To determine if the chemotherapy agents cisplatin, cytosine arabinoside (ARA-C) and Hydroxyurea when used together may be more effective in lung cancer patients than when used alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-10	**Status:**	Closed
Title:	SWOG 9215 - Quality of Life on Breast Cancer Adjuvant Trial				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective:

Technical Approach:

Number of subjects enrolled for reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-19	**Status:**	Ongoing
Title:	SWOG 9003 - Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: The objective of this study is to find out how well patients respond and how well patients respond and how long their response lasts when treated with Fludarabine. Fludarabine is now being evaluated to determine its benefits and effectiveness on Waldenstrom's Macroglobulinemia. We want to learn more about this disease and how long it can be observed without chemotherapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-20	**Status:**	Closed
Title:	SWOG 9015 - A Randomized Trial of Pre- and PostOperative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-Small Cell Carcinoma of the Lung, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC LTC Stephen Oswald, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To compare how well patients respond and how long the response lasts when treated with a combination of VP-16 and carboplatin before and after surgery or surgery alone, and to estimate the side effects of these drugs and how often they occur.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-21	**Status:**	Ongoing
Title:	SWOG 9201 - Phase III, Trial to Preserve the Larynx: Induction Chemotherapy and Radiation Therapy versus Radiation Therapy				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93, Feb 94, Continue			

Study Objective: To preserve the larynx by using non-surgical treatments. Three treatments will be compared: (1) chemotherapy followed by radiation, or (2) chemotherapy given at the same time, or (3) radiation alone.

Technical approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered during this reporting period.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-22	**Status:**	Ongoing
Title:	SWOG 9205 - Central Prostate Cancer Serum Repository Protocol				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93, Feb 94, Continue		

Study Objective: To serve as a repository for serum of patients with prostate cancer entered onto Southwest Oncology Group approved studies. The purpose of this activity is to provide the opportunity for study of new or existing markers or other tests in a prospective or retrospective fashion in order to test their usefulness as diagnostic or management tools in prostate cancer at all stages.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-28	**Status:**	Ongoing
Title:	SWOG 9158 - Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (Stage IV)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, M MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective:To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. To further define the qualitative and quantitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-29	**Status:**	Ongoing
Title:	SWOG 9216 - A Randomized Phase III Study of CODE Plus Thoracic Irradiation *versus* Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: overall survival, time to disease progression, response rate, response duration, and quality of life.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-43	**Status:**	Ongoing
Title:	SWOG 9126 - A Controlled Trial of Cyclosporine as a Chemotherapy-Resistance Modifier in High Risk Acute Myeloid Leukemia, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To compare the complete remission rate and duration of survival in patients with high-risk acute myeloid leukemia (AML), when treated with either chemotherapy (ara-C/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA): To estimate the frequency of p-glycoprotein expression and the correlation with prognosis in patients with relapsed AML, primary refractory AML, and secondary AML; to compare the frequency and severity of toxicity of the two treatment regimens; and to investigate the relationship between response to treatment and the blood levels of cyclosporine-A and daunorubicin achieved.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-44	**Status:**	Ongoing
Title:	SWOG 9237 - Evaluation of Topotecan in Refractory and Relapsing Multiple Myeloma, Phase II				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 94, Continue			

Study Objective: To evaluate the response rate for refractory myeloma treated with topotecan; the qualitative and quantitative toxicities of topotecan administered in a Phase II study; and measure topoisomerase levels in multiple myeloma cells.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-45	**Status:**	Closed
Title:	SWOG 9240 - A Phase II Trial of CVAD for Treatment of Non-Hodgkin's Lymphoma				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC MAJ Karen Bowen, MC COL Jayanti K. Sen, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 94, Continue			

Study Objective: To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of CVAD will be based on the estimate of the complete response rate and the time to treatment failure.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-46	**Status:**	Ongoing
Title:	SWOG 9246 - A Phase II Evaluation of Taxol in Patients with Relapsed Non-Hodgkin's Lymphoma or Relapsed Hodgkin's Disease				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To assess the response rate of relapsed low grade non-Hodgkin's lymphoma, relapsed intermediate or high grade non-Hodgkin's lymphoma and relapsed Hodgkin's disease treated with taxol and to assess the qualitative and quantitative toxicities of taxol administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-53	**Status:**	Ongoing
Title:	SWOG 9221 - Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-cRA) to Prevent Second Primary Tumors (SPTs) in Stage I Non-Small Cell Lung Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To compare daily oral administration of 13-Cis Retinoic Acid against placebo in preventing new primary lung tumors from patients having had surgical treatment of a Stage I non-small cell lung tumor.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-54	**Status:**	Closed
Title:	SWOG 9157 - Trial of All Trans-Retinoic Acid in Hepatoma, Phase II				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert F. Krywicki, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology				**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Feb 94, Continue	

Study Objective: To compare thrice daily oral administration of all trans-retinoic acid or placebo on three week cycles for hepatoma, a malignancy for which no good treatment exists. Evidence of efficacy will lead to a wider clinical study.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-55	**Status:**	Ongoing
Title:	SWOG 9210 - A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction; (2) Randomization of Prednisone Dose Intensity for Remission Maintenance				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine. It will evaluate the chemosensitizing potential of quinine to reverse drug resistance.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled duirng this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol**	93-56	**Status:**	Closed
Title:	SWOG 9248 - A Phase II Trial of Paclitaxel (Taxol) in Patients with Metastatic Refractory Carcinoma of the Breast				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): MAJ Robert F. Krywicki, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology				**Associate Investigators:** MAJ Don W. Shaffer, MC COL Charles T. Thornsvard, MC LTC Stephen G. Oswald, MC COL Jayanti K. Sen, MC MAJ Karen Bowen, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Feb 94, Continue	

Study Objective: To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. Information obtained from patients in studies like this one can, in the future, help a doctor and a patient make treatment decisions.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: One patient on study. No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-16	**Status:**	Ongoing
Title:	SWOG 9303 - Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC COL Jayanti Sen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To determine whether 5FU, levamisole and radiation therapy results in superior overall survival when compared to 5FU and levamisole without radiation therapy in the management of patients with completely resected pathologic stage (T4bNo-2) colon cancer and selected patients with (T3N1-2) colon cancer. Disease free survival, patterns of failure and toxicity will also be evaluated.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-17	**Status:**	Ongoing
Title:	SWOG 9306 - Conservative Treatment of Adenocarcinoma of the Distal Rectum: Local Resection Plus Adjuvant 5FU/Radiation Therapy, A Phase II Intergroup Study				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC COL Jayanti Sen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To determine whether the survival of patients with T1 and T2 adenocarcinoma of the rectum who have been treated with limited, sphincter sparing surgery is comparable to that of historical controls treated with radical surgery (abdominoperineal resection). This study will determine the efficacy and toxicity of a combined modality approach using conservative surgery with post-operative radiation therapy and 5-FU.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-21	**Status:**	Ongoing
Title:	SWOG 9005 - Double Blind Randomized Trial of the Anti-Progestational Agent Mifepristone in the Treatment of Unresectable Meningioma, Phase III				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 94, Continue			

Study Objective: To find out whether patients will respond and how long their response lasts if treated with the experimental antiprogestational agent mifepristone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1 (transfer from BAMC)

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-22	**Status:**	Ongoing
Title:	SWOG 9250 - Phase III Intergroup Prospectively Randomized Trial of Perioperative 5-FU after Curative Resection Followed by 5-FU/evamisole for Patients with Colon Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To determine if adjuvant therapy with one week of continuous 5-FU given within 24 hours of a curative colon resection followed by 12 months of 5-FU/levamisole is effective in prolonging the disease free interval and increasing survival in patients with Dukes B3 or C colon cancer, when compared to patients who are treated with 5-FU/levamisole only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-23	**Status:**	Ongoing
Title:	SWOG 9312 - Phase II Evaluation of Cisplatin + 5FU + Radiation Therapy in Patients with Locally Advanced/Inoperable Bladder Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To assess the response rate and the feasibility of utilizing cisplatin + 5FU + radiation therapy in patients with locally advanced/inoperable carcinoma of the bladder. This study will also assess the qualitative and quantitative toxicities of this combination.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-24	**Status:**	Ongoing

Title:	SWOG 9300 - A Randomized Phase II Evaluation of All Trans Retinoic Acid (ATRA) with Interferon-Alfa 2a (IFNOalfa 2a) or All Trans Retinoic Acid with Hydroxyurea (H) in Patients with Newly Diagnosed Chronic Myelogenous Leukemia in Chronic Phase
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): MAJ Robert F. Krywicki, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Feb 94, Continue

Study Objective: To find out how well patients respond and how long their response lasts when treated with either All Trans Retinoic Acid and hydroxyurea or All Trans Retinoic Acid and interferon. This study will also find out what kind of side effects these drugs cause and how often they occur; and examine the cells of the patient's bone marrow to find out if there is any connection between response to treatment and the type of cells that are identified in the bone marrow.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	10 Feb 94	**Protocol**	94-38	**Status:**	Ongoing
Title:	SWOG 9332 - Phase II Trial of Adriamycin versus Taxol versus Taxol plus Adriamycin Plus G-CSF in Metastatic Breast Cancer				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): MAJ Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To compare the activity of Taxol as a single agent with that of single-agent Adriamycin and with Adriamycin and Taxol in combination in patients with metastatic breast cancer, in an effort to determine the relative efficacy and toxicity of the three regimens in patients with previously untreated metastatic breast cancer. This study aims to (1) slow or stop the growth of the tumor, (2) gain information about the disease, (3) help identify better treatments for cancer of the breast, (4) help define the side effects and effectiveness of Taxol when it is used in combination with a commonly used chemotherapeutic agent for breast cancer, Adriamycin, and (5) assess changes in quality of life that occur while the patient is receiving treatment.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol**	94-45	**Status:**	Ongoing
Title:	SWOG 9308 - Randomized Trial Comparing Cisplatin Plus Intravenous Navelbine in the Treatment of Previously Untreated, Stage IV Non-Small Cell Lung Cancer Patients				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** COL Charles Thornsvard, MC MAJ Don Shaffer, MC MAJ Karen Bowen, MC LTC Stephen Oswald, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: The objectives of this Phase II study are to (1) compare the effect of cisplatin alone with that of intravenous Navelbine plus cisplatin on tumor response rate, survival, and time to treatment failure in patients with Stage IV non-small cell lung carcinoma, and (2) compare the toxicity of the two treatment regimens in patients with Stage IV non-small cell lung carcinoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1

Progress: One patient registered on protocol, but was taken off study due to spinal cord compression (not protocol related).

DETAIL SUMMARY SHEET

Date:	08 Sep 94	**Protocol**	94-73	**Status:**	Ongoing
Title:	SWOG 9307 - Extended Administration of Oral Etoposide and Oral Cyclophosphamide for the Treatment of Poor Prognosis Extensive Disease Small Cell Lung Cancer, Phase II Pilot				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** LTC Kenneth Fink, MC LTC Stephen Oswald, MC MAJ Karen Bowen, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 94, Continue		

Study Objective: To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in poor prognosis extensive disease small cell lung cancer; to evaluate the qualitative and quantitative toxicities of this regimen administered in a Phase II study; and to investigate possible correlations between peak and trough plasma etoposide levels versus complete response, toxicity, and survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-18	**Status:**	Ongoing
Title:	Treatment of Adult Patients with Chickenpox with Short Course Oral Acyclovir				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Steve Reissman, MC			**Facility:** USA MEDDAC, Fort Benning, Georgia		
Department/Service: Family Practice			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To determine if oral acyclovir, when used for five days, is effective in the treatment of adults who have chickenpox.

Technical Approach: As soon as a patient develops chickenpox, that patients will be sent to the hospital so as not to infect other soldiers and to rest. Each patient will have a 50/50 change of getting the drug acyclovir or a look alike placebo in addition to Tylenol and an anti-itch medicine. Each patient will be in the hospital for approximately 5-10 days which is the usual length of hospitalization for chickenpox. Each patient will have 1/2 ounce of blood drawn each day and will be asked several questions about his/her chickenpox. Additionally, all patients will have boxes drawn on their chest and back with a magic marker so that the number of chickenpox lesions can be counted in these boxes on a daily basis. Each patient will also have a picture taken of these boxes each day.

Number of subjects enrolled for the reporting period: Approximately 8

Progress: Slowly accumulating cases for protocol.

DETAIL SUMMARY SHEET

Date:	18 Nov 93	**Protocol**	94-19	**Status:**	Ongoing
Title:	Carbohydrate Deficient Transfervis as a Measure of Alcohol Use Among U.S. Army Personnel				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Gerald M. Cross, MC			**Facility:** USA MEDDAC, Fort Benning, Georgia		
Department/Service: Family Practice			**Associate Investigators:** MAJ Kim J. Zagorski, MC CPT Kelly A. Murray, MC John P. Allen, PhD, MPA Sidney Levine, PhD MAJ Marsha L. Bloodworth, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To explore four issues which have not been adequately addressed by previous investigations: 1) What specific patterns of alcohol use (quantity, frequency, duration, and recency) are identified by CDT elevation?, 2) How sensitive and specific is CDT elevation for the current population of younger adult subjects and how do these predictive values compare with those previously reported on generally older sample?, 3) Do age, gender or ethnicity moderate the relationship between alcohol intake and CDT level?, and 4) Does CDT level add meaningful information to the traditional biochemical tests, GGT, ALAT, and MCV and verbal screening measures, CAGE, SAAST, and AUDIT in predicting diagnosis of alcohol dependence, alcohol abuse, and non-problematic alcohol use?

Technical Approach: Three hundred subjects will be enrolled in the study. The sample will be stratified on the basis of self-reported time since last drink. One hundred twenty-five subjects will have consumed alcohol within the seven days before assessment; 125 between eight and fourteen days prior to assessment; and 50 between fifteen and twenty-one days before assessment. Subjects will be selected sequentially from individuals receiving the ADAPCP evaluation and in proportion to the required three subsample sizes. Two research assistants, trained by staff from the University of Connecticut in the Coordinating Center for Project MATCH, will conduct all assessments.

Number of subjects enrolled for the reporting period:

DETAIL SUMMARY SHEET

Date:	12 May 94	**Protocol**	94-56	**Status:**	Ongoing
Title:	Musculoskeletal Overuse Injury: Bone Mass and Fitness				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Todd Dombroski, MAJ, MC			**Facility:** Martin ACH, Fort Benning, Georgia		
Department/Service: Family Practice			**Associate Investigators:** Linda Shackelford Adrian LeBlanc		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To determine how levels of physical fitness prior to beginning an exercise training program affect development of overuse injury, markers for physical conditioning such as performance scores for situps and run on the initial Army Physical Readiness Test will be compared between a population with overuse injury and non-injury population.

Technical Approach: A population of 200 military recruits in the inprocessing period and first week of basic training and who exhibit no signs or symptoms of stress fracture, tendinitis, bursitis, plantar fascitis, or patellofemoral pain will be scanned with a dual beam x-ray bone densitometer on the Hologic 2000. They will be rescanned at the end of twelve week Army training program. Information will be obtained concerning age, sex and genetic pool. The 200 sample subjects will be divided into subpopulations according to starting bone density. The amount of change in trabecular bone density for each of the sample sub-populations will be compared to the population's starting density. Change in bone density will be plotted against trabecular stress fracture rate. Those who develop stress fractures will also be studied (about 340 in a year).

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	6 Oct 92	**Protocol**	78-14	**Status:**	Closed
Title:	Intraocular Lens Study				
Start Date:	Oct 81		**Est. Compl. Date:**		
Principal Investigator(s): Emil A. Stein, CPT, MC			**Facility:** USA MEDDAC, Ft Campbell, KY		
Department/Service: Surgery/Ophthalmology			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Subjects enrolled to date: 333
Subjects enrolled for the reporting period: 96

Progress: Principal investigator left service May 1993. Study closed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	**Protocol**	92-55	**Status:**	Complete
Title:	The effects of parental deployment on childhood behavior				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Marvin C. Arnold, MAJ, MS			**Facility:** USA MEDDAC, Ft Campbell, KY		
Department/Service: Psychiatry			**Associate Investigators:** Stephen N. Xenakis, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To determine those elements that impact on family functioning during deployment of the soldier, particularly on the children. To determine what neuro-psychological, social, and behavioral dysfunction occurred in children of deployed parents before, during and after Operation Desert Storm.

Technical Approach: (1) Experimental design: The study utilizes a stratified multi-cell (five cells) design. The population consists of parents of children in the following categories: single parents, dual career couples, intact/traditional families, parents of disturbed children (seen at Child Psychiatry, Community Mental Health Activity and Social Work Services during deployment), parents of nondisturbed children (seen at regular Family Practice visits). Stratified probability sampling will be employed to select the research sample. Sample size estimation is 200 subjects per cell. Sample size determination was made by selecting a population size (n) that is sufficient for the standard error of estimate not to exceed 0.05.

(2) Manpower: Consists of the Principal Investigator, a 91G Behavioral Science Specialist,a nd five research assistants employed at Blanchfield Army Hospital.

(3) Number of subjects enrolled: 1,836

Progress: One article submitted for review for publication. No problems were encountered.

DETAIL SUMMARY SHEET

Date:	8 Jul 93	**Protocol**	93-52	**Status:**	Terminated
Title:	Pregnancy Exercise Patterns and Post-partum Fitness				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Lori B. Newman, AN			**Facility:** USA MEDDAC, Ft Campbell, KY		
Department/Service:			**Associate Investigators:** Terence J. Caldwell, LTC, AN Bari C, Knobel, MAJ, AN Judith L. Chantelois, MAJ, MC Frank W. Montgomery, III, Asst Prof		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To describe pregnancy outcome measures in active duty women with various levels of self-directed or organized prenatal exercise.

Technical Approach: Compare the physical fitness test scores of active duty soldiers before and after experiencing pregnancy and childbirth.

Number of subjects enrolled for the reporting period:

Progress: Funding not approved; protocol terminated.

DETAIL SUMMARY SHEET

Date:	14 Apr 94	**Protocol**	94-46	**Status:**	Ongoing
Title:	Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Military Personnel with Documented Recent HIV Antibody Serconversion - Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Lynn Levine, PhD, MPH			**Facility:** WRAIMC, Washington, DC		
Department/Service: Medicine/Preventive Medicine			**Associate Investigators:** Jane Grimes, RN, MA		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To join a research study designed to determine specific factors that are associated with becoming infected with the Human Immunodeficiency Virus (HIV).

Technical Approach: Will compare survey responses of active duty Army personnel who have recently become positive for antibody to HIV with responses of active duty Army personnel who recently tested negative for the HIV antibody. Participants will use a laptop computer with headphones. The computer will play a recorded version of each questions in which the participant will answer on the keyboard. The survey will contain many items, including very personal questions about sexual and other behaviors.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	11 Mar 93	**Protocol**	93-33	**Status:**	Ongoing
Title:	Vocal Cord Function and Voice Quality Evaluation of Active Duty U.S. Army Drill Instructors				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Pearline McKenzie, CPT, MC			**Facility:** USA MEDDAC, Ft Jackson, SC		
Department/Service:			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To document the laryngeal pathology and record the acoustic effects of acute voice abuse in active duty US Army drill instructors during periods of intense training.

Technical Approach: Subjects will be chosen for videostroboscopy and acoustic analysis preceding and during the early phases of small unit training.

Number of subjects enrolled for the reporting period:

Progress: The principal investigator for this study has changed to CPT Pearline McKenzie at WRAMC, Head and Neck Surgery Service.

DETAIL SUMMARY SHEET

Date:	09 Sep 93	**Protocol**	93-60	**Status:**	Terminated
Title:	Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood-Pressure Control				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): LTC Myron Piziak, MS			**Facility:** USA MEDDAC, Ft Rucker, Alabama		
Department/Service: Pharmacy			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To access the comparability of clinical effects of Cardizem CD and Dilacor XR in the treatment of hypertension.

Technical Approach: The Food and Drug Administration has already found evidence of the safety and efficacy of these two dosage forms for this indication. Investigators will examine available medical records and maintain confidentiality.

Number of subjects enrolled for the reporting period:

Progress: Terminate at request of PI.

DETAIL SUMMARY SHEET

Date:	12 Aug 93	**Protocol**	93-58	**Status:**	Completed
Title:	Periodic Prenatal Nursing Interaction for Primigravidas: Does It Affect Preterm Birth Rate and Prental Care Compliance?				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Kathleen Ford, AN			**Facility:** USA MEDDAC, Ft Stewart, Georgia		
Department/Service: Nursing			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To examine empirically the relationship between regular telephonice nursing interaction with primigravidas during the antepartal period and the rate of preterm birth, as well as the level of prenatal care compliance in this population.

Technical Approach: The independent variable is the regular nursing telephonic interaction with the patient. Subjects will be randomly assigned to either the control or the experimental group. Treatment for the experimental group will consist of an initial face-to-face interview in the first trimester, followed by telephone interviews every two weeks until pregnancy is completed. The control group will have no treatment; their charts will be reviewed after delivery for outcome information.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	09 Dec 93	**Protocol**	94-26	**Status:**	Ongoing
Title:	A Proposed Study of the Validity of the PK and PS Scales of the MMPI-2: PTSD and Incest.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Diane M. Zierhoffer, CPT, MS			**Facility:** Fort Stewart, Georgia		
Department/Service: Psychology			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 94, Continue		

Objective: To better understand the results of the MMPI-2 as they relate to women.

Technical Approach: Three groups of women will be given the MMPI-2: (1) subject group of women currently in therapy who have experienced incest and diagnosed with PTSD; (2) women in therapy who deny having experienced incest and any other trauma, and (3) women not in therapy who deny a history of trauma and incest.

Number of subjects enrolled for the reporting period:

Progress: Data collection in progress.

AUTHOR INDEX

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